

# **Medicare Advantage Plans**

## **2021 Prior Authorization (PA)**

AdventHealth Advantage Plans is administered by Health First Health Plans. Health First Health Plans is an HMO plan with a Medicare Contract. Enrollment in Health First Health Plans depends on contract renewal.

Y0089\_MPINFO8785AH\_C(10/2020)

**Drugs**  
*acitretin*

**Exclusion Criteria**

Severely impaired liver or kidney function. Chronic abnormally elevated blood lipid values. Concomitant use of methotrexate or tetracyclines. Pregnancy. Females of child-bearing potential who intend to become pregnant during therapy or at any time for at least 3 years after discontinuing therapy. Females of child-bearing potential who will not use reliable contraception while undergoing treatment and for at least 3 years following discontinuation. Females of child-bearing potential who drink alcohol during treatment or for two months after cessation of therapy.

**Required Medical Information**

Diagnosis of severe psoriasis.

**Age Restriction**

18 years of age or older

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## ACTIMMUNE

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### **Drugs** **ACTIMMUNE**

#### **Exclusion Criteria**

Hypersensitivity to interferon gamma, E. coli derived proteins, or any component of the formulation.

#### **Required Medical Information**

Diagnosis of chronic granulomatous disease or severe malignant osteoporosis.

#### **Age Restriction**

#### **Prescriber Restriction**

#### **Coverage Duration**

Through end of benefit year.

#### **Other Criteria**

Home or LTC administration covered under Medicare Part D. Physician office or healthcare setting administration, redirect for Medicare Part B coverage.

#### **Indications**

All FDA-approved Indications.

#### **Off Label Uses**

**Drugs**  
**ADEMPAS**

**Exclusion Criteria**

Pregnancy. Concomitant administration with nitrates or nitric oxide donors (such as amyl nitrate) in any form.  
Concomitant administration with phosphodiesterase inhibitors, including specific PDE-5 inhibitors (such as sildenafil, tadalafil, or vardenafil) or non-specific PDE inhibitors (such as dipyridamole or theophylline).

**Required Medical Information**

**Age Restriction**

18 years of age or older

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

For renewal, medication was effective (i.e. improved 6 minute walk distance, oxygen saturation, etc.)

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## AFINITOR

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### Drugs

**AFINITOR, AFINITOR DISPERZ**, *everolimus (antineoplastic)*

### Exclusion Criteria

#### Required Medical Information

Diagnosis of one of the following: A) Advanced metastatic renal cell carcinoma and patient has failed therapy (disease progressed) with Sutent or Nexavar (Afinitor or everolimus), or B) Progressive pancreatic, nonfunctional GI or lung neuroendocrine tumors (NET) that are unresectable, locally advanced or metastatic (Afinitor or everolimus), or C) Renal angiomyolipoma with tuberous sclerosis complex (TSC) and patient does not require immediate surgery (Afinitor or everolimus), or D) Advanced hormone receptor-positive, HER2-negative breast cancer and patient is a postmenopausal woman and patient has failed treatment with Femara or Arimidex and the medication will be used in combination with Aromasin (Afinitor or everolimus), or E) Subependymal giant cell astrocytoma (SEGA) associated with TSC that requires therapeutic intervention but is not a candidate for curative surgical resection (Afinitor or Afinitor Disperz only), or F) TSC-associated partial-onset seizures (Afinitor Disperz only).

### Age Restriction

### Prescriber Restriction

### Coverage Duration

Through end of benefit year

### Other Criteria

### Indications

All FDA-approved Indications.

### Off Label Uses

## ALECENSA (alectinib)

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### **Drugs** **ALECENSA**

#### **Exclusion Criteria**

#### **Required Medical Information**

Documented diagnosis of anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) as detected by an FDA-approved test.

#### **Age Restriction**

#### **Prescriber Restriction**

#### **Coverage Duration**

Through end of benefit year

#### **Other Criteria**

#### **Indications**

All FDA-approved Indications.

#### **Off Label Uses**

## ALOSETRON

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### **Drugs**

*alosetron*

### **Exclusion Criteria**

Initial therapy for Irritable Bowel Syndrome (IBS) in the male gender.

### **Required Medical Information**

Diagnosis of irritable bowel syndrome with diarrhea and failed at least TWO alternatives from different classes such as antidiarrheals (e.g. loperamide), antispasmodics (e.g. dicyclomine). Reauthorization for Irritable Bowel Syndrome (IBS): 1. Recurrence of diarrhea predominant IBS, AND 2. documentation of positive clinical response while on alosetron.

### **Age Restriction**

18 years of age or older

### **Prescriber Restriction**

Prescriber must be specially trained gastrointestinal physician

### **Coverage Duration**

IBS Initial Therapy: 12 weeks Reauthorization: 6 months

### **Other Criteria**

Initial Therapy for Irritable Bowel Syndrome (IBS): 1. Failure to both: a. An antispasmodic (e.g. dicyclomine) AND b. An anti-diarrhea agent (e.g. loperamide, diphenoxylate-atropine).

### **Indications**

All FDA-approved Indications.

### **Off Label Uses**

**Drugs**

**ALUNBRIG ORAL TABLET 180 MG, 30 MG, 90 MG, ALUNBRIG ORAL TABLETS,DOSE PACK**

**Exclusion Criteria**

**Required Medical Information**

diagnosis of A) anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) who have progressed on or are intolerant to crizotinib OR B) tyrosine kinase inhibitor-naive advanced anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC).

**Age Restriction**

**Prescriber Restriction**

Oncologist

**Coverage Duration**

3 Months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**



**Drugs**

*dalfampridine*

**Exclusion Criteria**

History of seizure. Moderate or severe renal impairment (creatinine clearance less than or equal to 50 mL/minute). Patient currently using any other forms of 4-aminopyridine.

**Required Medical Information**

Diagnosis of multiple sclerosis AND patient is ambulatory (able to walk at least 25 feet) AND patient has walking impairment.

**Age Restriction**

**Prescriber Restriction**

Neurologist

**Coverage Duration**

Initial: 3 months. Renewal: through end of benefit year.

**Other Criteria**

For renewal, documentation that walking speed has improved from baseline must be provided.

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**ANADROL-50**

**Exclusion Criteria**

1. Carcinoma of the prostate or breast in male patients. 2. Carcinoma of the breast in females with hypercalcemia, androgenic anabolic steroids may stimulate osteolytic resorption of bones. 3. Pregnancy 4. Nephrosis or the nephrotic phase of nephritis. 5. Severe hepatic dysfunction.

**Required Medical Information**

Acquired Aplastic Anemia: 1. History of failure to erythropoietic stimulating agent, OR 2. Used in combination with antilymphocyte globulin or both antilymphocyte globulin and corticosteroid treatment. Hypoplastic Anemia: 1. Diagnosis of hypoplastic anemia due to myelotoxic drugs, AND 2. Failure to erythropoietic stimulating agent. Pure Red Cell Aplasia: Failure of immunosuppressive therapy. Anemia of Chronic Renal Failure: Failure to an erythropoietic stimulating agent. Preferred Erythropoietin Stimulating Agent: Procrit. Tablet should not replace correcting iron, folic acid, and vitamin B12.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## APOKYN

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### **Drugs** **APOKYN**

#### **Exclusion Criteria**

Use with 5HT3-antagonist (e.g., ondansetron, granisetron, dolasetron, palonosetron, alosetron).

#### **Required Medical Information**

##### **Age Restriction**

##### **Prescriber Restriction**

Neurologist for initial prescription

##### **Coverage Duration**

Through end of benefit year

##### **Other Criteria**

##### **Indications**

All FDA-approved Indications.

##### **Off Label Uses**

## APTIOM

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### Drugs APTIOM

#### Exclusion Criteria

#### Required Medical Information

Diagnosis of partial-onset seizures and treatment failure of at least two other formulary medications used in the treatment of partial onset seizures.

#### Age Restriction

#### Prescriber Restriction

Neurologist

#### Coverage Duration

Through end of benefit year

#### Other Criteria

#### Indications

All FDA-approved Indications.

#### Off Label Uses

## ARCALYST

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### **Drugs** **ARCALYST**

#### **Exclusion Criteria**

#### **Required Medical Information**

Diagnosis of cryopyrin-associated period syndromes (CAPS), including Familial Cold Auto-inflammatory Syndrome (FCAS) and/or Muckle-Wells Syndrome (MWS).

#### **Age Restriction**

12 years of age and older

#### **Prescriber Restriction**

Prescribed by or in consultation with or recommendation of, an immunologist, allergist, dermatologist, rheumatologist, neurologist, or other medical specialist.

#### **Coverage Duration**

Through end of benefit year

#### **Other Criteria**

Approve doses based on FDA labeling.

#### **Indications**

All FDA-approved Indications.

#### **Off Label Uses**

**Drugs**  
**AUBAGIO**

**Exclusion Criteria**

Treatment of primary progressive MS is not covered. Combination therapy with a beta interferon product, Gilenya, Aubagio, Tecfidera, Tysabri or Copaxone is not covered.

**Required Medical Information**

Diagnosis of relapsing forms of multiple sclerosis (relapsing-remitting MS or progressive-relapsing MS, or secondary-progressive MS) OR patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year.

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## Austedo

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### Drugs

AUSTEDO ORAL TABLET 12 MG, 6 MG, 9 MG

### Exclusion Criteria

#### Required Medical Information

Documented diagnosis of 1) chorea associated with Huntington's disease OR 2) tardive dyskinesia

#### Age Restriction

18 years of age or older

#### Prescriber Restriction

#### Coverage Duration

3 Months

#### Other Criteria

#### Indications

All FDA-approved Indications.

#### Off Label Uses

**Drugs**

**AVONEX INTRAMUSCULAR PEN INJECTOR KIT, AVONEX INTRAMUSCULAR SYRINGE KIT**

**Exclusion Criteria**

Treatment of primary progressive MS is not covered. Combination therapy with a beta interferon product, Gilenya, Aubagio, Tecfidera, Tysabri or Copaxone is not covered.

**Required Medical Information**

Diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease OR diagnosis of first clinical episode and MRI features consistent with multiple sclerosis

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**



**Drugs**  
**AYVAKIT**

**Exclusion Criteria**

**Required Medical Information**

documentation of unresectable or metastatic GIST harboring a platelet-derived growth factor receptor alpha (PDGFRA) exon 18 mutation.

**Age Restriction**

**Prescriber Restriction**

Oncology

**Coverage Duration**

3 months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**BALVERSA**

**Exclusion Criteria**

**Required Medical Information**

Documented diagnosis of locally advanced or metastatic urothelial carcinoma AND member has susceptible FGFR3 or FGFR2 genetic alteration as detected by an FDA-approved companion diagnostic AND disease has progressed during or following at least one line of prior platinum-containing chemotherapy including within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy.

**Age Restriction**

18 years or older

**Prescriber Restriction**

**Coverage Duration**

3 Months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## BANZEL

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### Drugs

**BANZEL ORAL SUSPENSION, BANZEL ORAL TABLET 200 MG, 400 MG**, *rufinamide*

### Exclusion Criteria

Banzel (rufinamide) is not covered for members with the diagnosis of Familial Short QT syndrome

### Required Medical Information

Diagnosis of Lennox- Gastaut syndrome. Documentation of previous therapies and that the current medication regimen is inadequate to control disease.

### Age Restriction

Must be 1 years of age or older

### Prescriber Restriction

### Coverage Duration

Through end of benefit year

### Other Criteria

Patient must be refractory to at least 2 of the following: Felbamate (Felbatol), Lamotrigine (Lamictal), Topiramate (Topamax), Valproic acid (Depakene), Divalproex sodium (Depakote)

### Indications

All FDA-approved Indications.

### Off Label Uses

**Drugs**  
**BENLYSTA SUBCUTANEOUS**

**Exclusion Criteria**

Benlysta (belimumab) therapy is not considered medically necessary for members with the following concomitant conditions: severe active lupus nephritis, severe active central nervous system lupus, or in combination with other biologic products (examples include Humira, Enbrel, Remicade, Rituxan, Stelara, Cimzia, Kineret, Amevive, Orencia, Simponi, Actemra), including B-cell targeted therapies or intravenous (IV) cyclophosphamide.

**Required Medical Information**

This agent may be considered medically necessary when the following criteria are met: Systemic Lupus Erythematosus (SLE). The member must have a diagnosis of active systemic lupus erythematosus (SLE). The member must be auto-antibody positive in the absence of any drugs for SLE defined as: ANA titer greater than or equal 1:80 or anti-dsDNA level greater than or equal 30 I/mL. The member must be utilizing Benlysta (belimumab) in combination with standard treatment regimens for SLE which may include: corticosteroids (ex: prednisone), hydroxychloroquine, azathioprine.

**Age Restriction**

18 years of age and older

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## **Benznidazole**

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### **Drugs**

*benznidazole*

### **Exclusion Criteria**

Patients who have used disulfiram within two weeks of initiation of benznidazole

### **Required Medical Information**

Documentation of a consultation with an infectious disease specialist. Reviewer will verify patient claim history to confirm that patient has not used disulfiram within two weeks prior to benznidazole initiation

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

60 days

### **Other Criteria**

### **Indications**

All FDA-approved Indications.

### **Off Label Uses**

## BETASERON

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### **Drugs**

#### **BETASERON SUBCUTANEOUS KIT**

### **Exclusion Criteria**

Treatment of primary progressive MS is not covered. Combination therapy with a beta interferon product, Gilenya, Aubagio, Tecfidera, Tysabri or Copaxone is not covered.

### **Required Medical Information**

Diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease OR diagnosis of first clinical episode and MRI features consistent with multiple sclerosis.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

Through end of benefit year

### **Other Criteria**

### **Indications**

All FDA-approved Indications.

### **Off Label Uses**

## BOSULIF

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### Drugs

**BOSULIF ORAL TABLET 100 MG, 400 MG, 500 MG**

### Exclusion Criteria

Coverage is not provided in those that have the BCR-ABL1 T315I mutation and use of Bosulif in combination with other kinase inhibitors (for example sorafenib, sunitinib, etc.)

### Required Medical Information

Diagnosis of Philadelphia chromosome-positive chronic myelogenous leukemia.

### Age Restriction

18 years of age and older

### Prescriber Restriction

Hematologist/Oncologist

### Coverage Duration

3 Months

### Other Criteria

### Indications

All FDA-approved Indications.

### Off Label Uses

## Braftovi (Encorafenib)

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### Drugs

**BRAFTOVI ORAL CAPSULE 75 MG**

### Exclusion Criteria

#### Required Medical Information

Documentation of 1)unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test and the medication will be used in combination with binimetinib OR 2)metastatic colorectal cancer (CRC) with a BRAF V600E mutation and the medication will be used in combination with cetuximab.

### Age Restriction

#### Prescriber Restriction

Oncology

#### Coverage Duration

3 months

### Other Criteria

#### Indications

All FDA-approved Indications.

### Off Label Uses



## Brand Antipsychotics

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### Drugs

ABILIFY MAINTENA, ARISTADA INTRAMUSCULAR SUSPENSION,EXTENDED REL SYRING 441 MG/1.6 ML, CAPLYTA, GEODON INTRAMUSCULAR, REXULTI, ZYPREXA RELPREVV INTRAMUSCULAR SUSPENSION FOR RECONSTITUTION 210 MG

### Exclusion Criteria

#### Required Medical Information

Documented trial of any of the two following drugs: aripiprazole, clozapine, olanzapine, risperidone, quetiapine, ziprasidone

### Age Restriction

### Prescriber Restriction

#### Coverage Duration

Through end of benefit year

### Other Criteria

#### Indications

All FDA-approved Indications.

### Off Label Uses

## BRIVIACT (brivaracetam)

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### Drugs

BRIVIACT ORAL SOLUTION, BRIVIACT ORAL TABLET 10 MG, 100 MG, 25 MG, 50 MG, 75 MG

### Exclusion Criteria

#### Required Medical Information

Diagnosed with partial-onset seizures and treatment failure of at least two other formulary medications used in the treatment of partial onset seizures.

### Age Restriction

#### Prescriber Restriction

Neurologist

#### Coverage Duration

Through end of benefit year.

### Other Criteria

#### Indications

All FDA-approved Indications.

### Off Label Uses

**Drugs**  
**BRUKINSA**

**Exclusion Criteria**

**Required Medical Information**

Documentation of mantle cell lymphoma (MCL) in patients who have received at least one prior therapy.

**Age Restriction**

**Prescriber Restriction**

Oncology

**Coverage Duration**

3 Months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## BUPHENYL

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### **Drugs**

*sodium phenylbutyrate oral tablet*

### **Exclusion Criteria**

#### **Required Medical Information**

Diagnosis of urea cycle disorder (UCD) was confirmed by enzymatic, biochemical or genetic testing. Requested drug will be used for chronic management of UCD.

### **Age Restriction**

### **Prescriber Restriction**

#### **Coverage Duration**

Three months. Renewable with documentation of benefit.

### **Other Criteria**

#### **Indications**

All FDA-approved Indications.

### **Off Label Uses**

## BUTALBITAL CONTAINING PRODUCTS

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### Drugs

TENCON ORAL TABLET 50-325 MG, VTOL LQ

### Exclusion Criteria

#### Required Medical Information

Medical documentation of FDA-approved indication, AND trial and failure or contraindication to one preferred alternatives. Preferred alternatives include: NSAIDs such as ibuprofen.

#### Age Restriction

PA applies to patients 65 years or older

#### Prescriber Restriction

#### Coverage Duration

Through benefit year

#### Other Criteria

#### Indications

All FDA-approved Indications.

#### Off Label Uses

**Drugs**  
**BYNFEZIA**

**Exclusion Criteria**

**Required Medical Information**

To be used to treat of the following •Treatment of severe diarrhea/flushing episodes associated with metastatic carcinoid tumors in adult patients•Treatment of profuse watery diarrhea associated with vasoactive intestinal peptide tumors (VIPomas) in adult patients•To reduce the amount of growth hormone and insulin like growth factor 1 in adult patients with acromegaly who have had inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**CABLIVI INJECTION KIT**

**Exclusion Criteria**

**Required Medical Information**

Documented diagnosis of acquired thrombotic thrombocytopenic purpura (aTTP) AND must be used in combination with plasma exchange and immunosuppressive therapy (such as systemic corticosteroids or rituximab)

**Age Restriction**

18 years of age or older

**Prescriber Restriction**

hematologist

**Coverage Duration**

120 days

**Other Criteria**

Reauthorization: additional therapy up to a maximum 28 additional days will be approved with documentation of remaining signs of persistent underlying disease (such as suppressed ADAMTS13 activity levels)

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## CABOMETYX (cabozantinib)

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### Drugs

CABOMETYX ORAL TABLET 20 MG, 40 MG, 60 MG

### Exclusion Criteria

#### Required Medical Information

Diagnosis of advanced renal cell carcinoma (RCC) or hepatocellular carcinoma in patients who have been previously treated with sorafenib.

### Age Restriction

### Prescriber Restriction

### Coverage Duration

3 months

### Other Criteria

### Indications

All FDA-approved Indications.

### Off Label Uses



**Drugs**

**AIMOVIG AUTOINJECTOR, AJOVY AUTOINJECTOR, AJOVY SYRINGE**

**Exclusion Criteria**

**Required Medical Information**

Clinical documentation of migraines and member has tried and failed two formulary alternatives for migraine prophylaxis with two different mechanism of action such as Beta Blockers (metoprolol and propranolol), Antidepressants (amitriptyline and venlafaxine), Anticonvulsants (valproate and topiramate), Calcium Channel Blockers (verapamil and diltiazem), and Angiotensin-converting enzyme inhibitors/ angiotensin II receptor blockers (losartan and lisinopril). .

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**CALQUENCE**

**Exclusion Criteria**

**Required Medical Information**

Documented diagnosis of 1) mantle cell lymphoma (MCL) who have received at least one prior therapy OR 2) chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL)

**Age Restriction**

**Prescriber Restriction**

Oncologist or hematologist

**Coverage Duration**

3 Months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## CANCIDAS

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### Drugs

**CANCIDAS**, *caspofungin*

### Exclusion Criteria

#### Required Medical Information

Diagnosis of one of the following: A)Empirical therapy for presumed fungal infections in febrile, neutropenic patients, or B)Treatment of candidemia and other *Candida* infections (intraabdominal abscesses, peritonitis and pleural space infections), or C)Treatment of esophageal candidiasis, or D)Treatment of invasive aspergillosis in patients who are refractory to or intolerant of other therapies (amphotericin B, itraconazole).

#### Age Restriction

3 months of age or older

#### Prescriber Restriction

#### Coverage Duration

3 months

#### Other Criteria

#### Indications

All FDA-approved Indications.

#### Off Label Uses

## CAPRELSA

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### Drugs

**CAPRELSA ORAL TABLET 100 MG, 300 MG**

### Exclusion Criteria

Congenital long QT syndrome

### Required Medical Information

Diagnosis of symptomatic or progressive medullary thyroid cancer with unresectable locally advanced or metastatic disease.

### Age Restriction

18 years or older

### Prescriber Restriction

Oncologist or endocrinologist

### Coverage Duration

3 Months

### Other Criteria

### Indications

All FDA-approved Indications.

### Off Label Uses

## CARBAGLU

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### **Drugs** **CARBAGLU**

#### **Exclusion Criteria**

#### **Required Medical Information**

Diagnosis of NAGS deficiency was confirmed by enzymatic or genetic testing.

#### **Age Restriction**

#### **Prescriber Restriction**

#### **Coverage Duration**

Through end of benefit year

#### **Other Criteria**

#### **Indications**

All FDA-approved Indications.

#### **Off Label Uses**

**Drugs**  
**CAYSTON**

**Exclusion Criteria**

**Required Medical Information**

Diagnosis of cystic fibrosis AND patient has evidence of P. aeruginosa in the lungs

**Age Restriction**

7 years of age and older

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

For renewal, Patient is benefiting from treatment (i.e. improvement in lung function [FEV1], decreased number of pulmonary exacerbations)

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**CINRYZE**

**Exclusion Criteria**

**Required Medical Information**

Diagnostic laboratory testing for HAE has been performed (eg, C4, C1 inhibitor functional, and C1 inhibitor antigenic protein levels). For patients with HAE with C1 inhibitor deficiency, C1 inhibitor antigenic protein level and/or C1 inhibitor functional level is below the lower limit of normal as defined by the laboratory performing the test. For patients with HAE with normal C1 inhibitor, other causes of angioedema have been ruled out (eg, drug-induced) and EITHER 1) Patient tested positive for the F12 gene mutation OR 2) Patient has a family history of angioedema and the angioedema was refractory to a trial of antihistamine (eg, levocetirizine) for at least one month.

**Age Restriction**

**Prescriber Restriction**

Must be prescribed by Dermatologist, Hematologist, or Allergist/Immunologist

**Coverage Duration**

3 months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## CLOVIQUE (Trientine)

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### **Drugs** **CLOVIQUE**

#### **Exclusion Criteria**

Not recommended in cystinuria or rheumatoid arthritis. Not indicated for biliary cirrhosis.

#### **Required Medical Information**

For use in patients with diagnosis of Wilson disease who are intolerant to penicillamine.

#### **Age Restriction**

Geriatric patients: Use with caution. Initiate at lower end of the dosing range. Pediatric dosage: Children and adolescents:  
Oral: Initial: 20 mg/kg/day (round dose to the nearest 250 mg) in 2 to 3 divided doses. Maximum initial daily dose: 1,000 mg/day. titrate dose based on clinical response and free serum copper (non-ceruloplasmin bound copper) concentrations and/or 24-hour urinary copper excretion. usual maintenance dose: 900 to 1,500 mg/day in 2 to 3 divided doses

#### **Prescriber Restriction**

#### **Coverage Duration**

Through end of benefit year.

#### **Other Criteria**

#### **Indications**

All FDA-approved Indications.

#### **Off Label Uses**



**Drugs**

COMETRIQ ORAL CAPSULE 100 MG/DAY(80 MG X1-20 MG X1), 140 MG/DAY(80 MG X1-20 MG X3), 60 MG/DAY (20 MG X 3/DAY)

**Exclusion Criteria**

Gastrointestinal perforation. Fistula. Severe hemorrhage.

**Required Medical Information**

Diagnosis of progressive metastatic, medullary thyroid cancer.

**Age Restriction**

18 years or older

**Prescriber Restriction**

Oncologist/Hematologist

**Coverage Duration**

3 Months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## COPAXONE

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### **Drugs**

*glatiramer subcutaneous syringe 20 mg/mL, 40 mg/mL*, **GLATOPA SUBCUTANEOUS SYRINGE 20 MG/ML, 40 MG/ML**

### **Exclusion Criteria**

Treatment of primary progressive MS is not covered. Combination therapy with a beta interferon product, Gilenya, Aubagio, Tecfidera, Tysabri or Copaxone is not covered.

### **Required Medical Information**

Diagnosis of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease OR diagnosis of first clinical episode with MRI features consistent with multiple sclerosis.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

Through end of benefit year

### **Other Criteria**

### **Indications**

All FDA-approved Indications.

### **Off Label Uses**

**Drugs**  
**COPIKTRA**

**Exclusion Criteria**

**Required Medical Information**

Documentation of the following: A) relapsed or refractory CLL or SLL after at least two prior therapies OR B)relapsed or refractory FL after at least two prior systemic therapies.

**Age Restriction**

**Prescriber Restriction**

Oncology

**Coverage Duration**

3 months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**CORLANOR**

**Exclusion Criteria**

**Required Medical Information**

Must be clinically diagnosed with A) stable, symptomatic chronic heart failure in adults with left ventricular ejection fraction less than or equal to 35% supported by documentation from the patient's medical records, AND have sinus rhythm with resting heart rate greater than or equal to 70 beats per minute, AND be on maximally tolerated doses of beta blockers unless contraindicated OR B) stable symptomatic heart failure due to dilated cardiomyopathy (DCM) in pediatric patients aged 6 months and older AND have sinus rhythm with an elevated heart rate.

**Age Restriction**

**Prescriber Restriction**

Cardiologist

**Coverage Duration**

Through end of benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**

**COSENTYX (2 SYRINGES), COSENTYX PEN (2 PENS)**

**Exclusion Criteria**

**Required Medical Information**

Documented that patient is free of any clinically important active infections.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Initial Authorization will be for 3 months. Reauthorization will be for 1 year.

**Other Criteria**

Criteria and quantity restrictions will be applied consistent with current FDA-approved doses and indications.

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**COTELLIC**

**Exclusion Criteria**

**Required Medical Information**

Documented unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, in combination with vemurafenib.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year.

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## CYSTAGON

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### Drugs CYSTAGON

#### Exclusion Criteria

#### Required Medical Information

Diagnosis of nephropathic cystinosis confirmed by the presence of increased cystine concentration in leukocytes or by genetic testing.

#### Age Restriction

#### Prescriber Restriction

#### Coverage Duration

3 Months

#### Other Criteria

#### Indications

All FDA-approved Indications.

#### Off Label Uses

**Drugs**  
**CYSTARAN**

**Exclusion Criteria**

**Required Medical Information**

Diagnosis of cystinosis was confirmed by the presence of increased cystine concentration in leukocytes or by DNA testing. The patient has corneal cystine crystal accumulation.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year.

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**



## Daurismo (Glasdegib)

---

### Drugs

DAURISMO ORAL TABLET 100 MG, 25 MG

### Exclusion Criteria

#### Required Medical Information

Documentation that the medication will be used in combination with low-dose cytarabine for the treatment of newly-diagnosed acute myeloid leukemia (AML), and the patient is A) 75 years of age or older OR B) has comorbidities that preclude use of intensive induction chemotherapy.

### Age Restriction

#### Prescriber Restriction

oncology

#### Coverage Duration

3 months

### Other Criteria

#### Indications

All FDA-approved Indications.

### Off Label Uses

## Deferiprone

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### **Drugs**

*deferiprone*

### **Exclusion Criteria**

#### **Required Medical Information**

To be used only for the diagnosis of transfusional iron overload.

### **Age Restriction**

### **Prescriber Restriction**

#### **Coverage Duration**

Through end of benefit year

#### **Other Criteria**

Must be used within FDA approved dosing guidelines. Maximum dose: 99 mg/kg/day.

#### **Indications**

All FDA-approved Indications.

### **Off Label Uses**

**Drugs**  
**DEMSER**

**Exclusion Criteria**

**Required Medical Information**

Statement of diagnosis. Must have surgical resection planned, have a contraindication to surgery, or have malignant pheochromocytoma. For reauthorization: must have chart documentation from prescriber indicating improvement in condition.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Initial: 90 days. Reauthorization: through end of benefit year.

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**DIACOMIT**

**Exclusion Criteria**

**Required Medical Information**

Documented diagnosis of Dravet syndrome AND that the medication will be used as an add-on therapy to clobazam for seizures associated with Dravet syndrome.

**Age Restriction**

2 years and older

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

Medication will be used within FDA approved dosing guidelines. Maximum recommended dose: 3,000mg/day.

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## DIFICID

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### **Drugs** **DIFICID ORAL TABLET**

#### **Exclusion Criteria**

#### **Required Medical Information**

Diagnosis of Clostridium difficile associated diarrhea (CDAD) with one of the following: A) Patient has mild to moderate CDAD and failure, contraindication or intolerance to oral Vancocin (vancomycin), or B) Patient has severe CDAD.

#### **Age Restriction**

#### **Prescriber Restriction**

#### **Coverage Duration**

10 Days

#### **Other Criteria**

#### **Indications**

All FDA-approved Indications.

#### **Off Label Uses**

## Dimethyl Fumarate

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### Drugs

*dimethyl fumarate oral capsule, delayed release(DR/EC) 120 mg, 240 mg*

### Exclusion Criteria

Treatment of primary progressive MS is not covered. Combination therapy with a beta interferon product, Gilenya, Aubagio, Tecfidera, Tysabri or Copaxone is not covered.

### Required Medical Information

Diagnosis of relapsing forms of multiple sclerosis (relapsing-remitting MS or progressive-relapsing MS, or secondary-progressive MS) OR patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis.

### Age Restriction

### Prescriber Restriction

### Coverage Duration

Through end of benefit year

### Other Criteria

### Indications

All FDA-approved Indications.

### Off Label Uses

## DOPTELET (avatrombopag)

---

### Drugs

DOPTELET (10 TAB PACK), DOPTELET (15 TAB PACK), DOPTELET (30 TAB PACK)

### Exclusion Criteria

#### Required Medical Information

Documented diagnosis of A)Chronic liver disease, AND has thrombocytopenia with platelet count less than  $50 \times 10^9/L$ , AND is scheduled to undergo a procedure within 10 to 13 days after starting Doptelet therapy OR B)Chronic immune thrombocytopenia in patients who have had an insufficient response to a previous treatment.

#### Age Restriction

Greater than or equal to 18 years of age

#### Prescriber Restriction

#### Coverage Duration

End of benefit year

#### Other Criteria

#### Indications

All FDA-approved Indications.

#### Off Label Uses

### **Drugs**

*dronabinol*

### **Exclusion Criteria**

#### **Required Medical Information**

Diagnosis of one of the following: A) Treatment of chemotherapy-induced nausea and vomiting refractory to conventional antiemetic agents (i.e. ondansetron, granisetron, dexamethasone, aprepitant), or B) Treatment of anorexia associated with weight loss in patients with HIV with documented trial and failure, contraindication, or intolerance to megestrol.

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

Through end of benefit year.

### **Other Criteria**

Dronabinol is subject to Part B vs. Part D review. Part B if related to cancer treatment and is a full replacement for IV antiemetic within 48 hours of cancer treatment. Part D if related to cancer treatment after the 48-hour period, or for any other medically accepted diagnosis.

### **Indications**

All FDA-approved Indications.

### **Off Label Uses**



## Dupixent (Dupilumab)

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### Drugs

DUPIXENT PEN, DUPIXENT SYRINGE SUBCUTANEOUS SYRINGE 200 MG/1.14 ML, 300 MG/2 ML

### Exclusion Criteria

#### Required Medical Information

Patient must have the following: A) Moderate-to-severe atopic dermatitis (eczema) AND submission of medical records (e.g. chart notes, laboratory values) documenting the following: Inadequate response, intolerance or contraindication to ONE medication in EACH of the following categories: a. Topical calcineurin inhibitor b. High potency topical corticosteroid. OR B) Moderate-to-severe asthma AND submission of medical records documenting the following: 1. Patient has ONE of the following: a. Asthma with eosinophilic phenotype, or b. Oral corticosteroid dependent asthma with at least 1 month of oral corticosteroid use within the last 3 months AND 2. Inadequate control of asthma symptoms after a minimum of 3 months of use of one of the following: a. Inhaled corticosteroids & long acting beta agonist, or b. Inhaled corticosteroids & long acting muscarinic antagonist. OR C) chronic rhinosinusitis with nasal polyposis.

#### Age Restriction

patients 6 years of age and older for atopic dermatitis, 12 years of age and older for asthma, and adults for chronic rhinosinusitis with nasal polyposis.

#### Prescriber Restriction

#### Coverage Duration

Initial Authorization will be for 3 months. Reauthorization will be for 1 year.

#### Other Criteria

Renewals require submission of medical records (e.g. chart notes, laboratory values) documenting improvement of the condition.

#### Indications

All FDA-approved Indications.

#### Off Label Uses

**Drugs**  
**EMSAM**

**Exclusion Criteria**

Pheochromocytoma. Patient is taking or will take any of the following: SSRIs, SNRIs, tricyclic antidepressants (TCAs), bupropion, buspirone, meperidine, tramadol, methadone, pentazocine, dextromethorphan, St. John's wort, mirtazapine, cyclobenzaprine, oral selegiline, other MAOIs, oxcarbazepine, carbamazepine, and/or sympathomimetic amines.

**Required Medical Information**

Diagnosis of major depressive disorder, AND 1) Failure of at least two generic oral antidepressants from different classes (at least one should be from the following list: selective serotonin reuptake inhibitors, serotonin and norepinephrine reuptake inhibitors, mirtazapine, or bupropion unless contraindicated), AND 2) Patient had an adequate washout period (for patients previously on agents requiring a washout period)

**Age Restriction**

18 years old and greater

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**

**ENBREL MINI, ENBREL SUBCUTANEOUS RECON SOLN, ENBREL SUBCUTANEOUS SOLUTION, ENBREL SUBCUTANEOUS SYRINGE 25 MG/0.5 ML (0.5), 50 MG/ML (1 ML), ENBREL SURECLICK**

**Exclusion Criteria**

Active serious infection (including tuberculosis).

**Required Medical Information**

Diagnosis of one of the following: A) Moderate to severe rheumatoid arthritis and patient had an inadequate response to, intolerance to, or contraindication to at least one non-biologic disease modifying anti-rheumatic drugs (DMARD) and one NSAID for at least 3 months, or B) Moderate to severe polyarticular juvenile idiopathic arthritis and patient had an inadequate response, intolerance or contraindication to at least one DMARD and one NSAID for at least 3 months, OR C) Psoriatic arthritis and patient had an inadequate response, intolerance, or contraindication to methotrexate, or D) Ankylosing spondylitis and patient had an inadequate response, intolerance or contraindication to at least two NSAIDs, or E) Moderate to severe chronic plaque psoriasis (affecting more than 5% of body surface area or affecting crucial body areas such as the hands, feet, face, or genitals) and patient had an inadequate response, intolerance or contraindication to conventional therapy with to at least two of the following: phototherapy (including but not limited to Ultraviolet A with a psoralen [PUVA] and/or retinoids [RePUVA] for at least one continuous month or one or more oral systemic treatments (i.e. methotrexate, cyclosporine, acitretin, sulfasalazine) for at least 3 months.

**Age Restriction**

2 years of age or older for JIA. 4 years of age or older for plaque psoriasis. 18 years of age or older for all other indications.

**Prescriber Restriction****Coverage Duration**

Through end of benefit year

**Other Criteria**

Preferred NSAIDs include: ibuprofen, naproxen, ketoprofen, meloxicam. Preferred DMARDs include: methotrexate, sulfasalazine, hydroxychloroquine, cuprimine, azathioprine, leflunomide. Dosing as per FDA approved labeling.

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## Endari (Glutamine Powder)

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### **Drugs** **ENDARI**

#### **Exclusion Criteria**

#### **Required Medical Information**

Documented diagnosis of sickle cell disease.

#### **Age Restriction**

5 years and older

#### **Prescriber Restriction**

#### **Coverage Duration**

Through end of benefit year

#### **Other Criteria**

#### **Indications**

All FDA-approved Indications.

#### **Off Label Uses**

**Drugs**  
**ENSPRYNG**

**Exclusion Criteria**

**Required Medical Information**

Requires diagnosis of Neuromyelitis optica spectrum disorder

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**EPIDIOLEX**

**Exclusion Criteria**

**Required Medical Information**

Documentation of the following A) diagnosis of seizures associated with Lennox-Gastaut syndrome (LGS), Dravet syndrome (DS), or tuberous sclerosis complex (TSC): AND B) normal serum transaminases (ALT and AST) and total bilirubin levels: AND C) inadequate treatment response, intolerance, or contraindication to TWO generic antiepileptic medications (i.e. clobazam, Valproic acid, Lamotrigine, Levetiracetam, Topiramate, etc.)

**Age Restriction**

1 year of age or older

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

Dosing is within the FDA labeled dose of up to 20mg/kg/day.

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**

**PROCRIT INJECTION SOLUTION 10,000 UNIT/ML, 2,000 UNIT/ML, 20,000 UNIT/ML, 3,000 UNIT/ML, 4,000 UNIT/ML, 40,000 UNIT/ML**

**Exclusion Criteria**

Uncontrolled hypertension. Pure red cell aplasia that begins after ESA treatment.

**Required Medical Information**

Pre-treatment hemoglobin level less than 10 g/dL OR 15 g/dL for patients undergoing elective noncardiac, nonvascular surgery AND Patient has adequate iron stores prior to initiation of therapy defined as ferritin more than 100 mcg/L or serum transferrin saturation greater than 20% AND other causes of anemia such as iron deficiency, folate deficiency or B12 deficiency, hemolysis, gastrointestinal bleeding, other active or occult bleeding, or underlying hematologic disease (such as sickle cell anemia, thalassemia, and porphyria) have been ruled out AND Diagnosis of one of the following: A) Anemia due to chronic kidney disease (CKD) with or without hemodialysis, OR B) Anemia in patients with non-myeloid malignancies where anemia is due to the effect of concomitant myelosuppressive chemotherapy and two additional months of chemotherapy is anticipated, C) Treatment of anemic in a patient at high risk for perioperative blood loss from elective, noncardiac, nonvascular surgery to reduce the need for allogeneic blood transfusion, D) Anemia in zidovudine-treated HIV infection with serum erythropoietin levels 500 mUnits/mL or less and zidovudine doses 4,200 mg/week or less.

**Age Restriction**

**Prescriber Restriction**

CKD - prescribed by a nephrologist or hematologist. Non-myeloid malignancies - prescribed by an oncologist/hematologist. Surgery - Prescribed by a surgeon. HIV - Prescribed by an infectious disease specialist.

**Coverage Duration**

Initial: 3 months. Renewal: CKD-12 months, Non-myeloid cancers, HIV-4 months. Surgery-3 months

**Other Criteria**

For renewal of CKD (dialysis patients): Hb less than 11 g/dL or physician will decrease or interrupt dose. For renewal of CKD (non-dialysis patients): Hb less than 10 g/dL or physician will decrease or interrupt dose. For renewal of non-myeloid malignancies: Concurrent myelosuppressive chemotherapy and Hb is 12g/dL or less and there is measurable response after eight weeks (defined as an increase in Hb 1 g/dL or more or a reduction in red blood cell transfusion requirements). For renewal of zidovudine-treated HIV, Hb is 12g/dL or less AND Zidovudine dose remains 4,200 mg/week or less and there is a measurable response after eight weeks (defined as an increase in Hb or a reduction in RBC transfusion requirements or documented dose escalation [up to max of 300 units/kg/dose]). Subject to Part D versus Part B coverage determination.

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**ERIVEDGE**

**Exclusion Criteria**

**Required Medical Information**

Diagnosis of metastatic basal cell carcinoma OR Diagnosis of locally advanced basal cell carcinoma that has recurred following surgery or when the patient is not a candidate for surgery and radiation.

**Age Restriction**

18 years or older

**Prescriber Restriction**

**Coverage Duration**

3 months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**



**Drugs**  
**ERLEADA**

**Exclusion Criteria**

**Required Medical Information**

Documented diagnosis of 1) non-metastatic, castration-resistant prostate cancer (NM-CRPC) OR 2) metastatic castration-sensitive prostate cancer.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

3 Months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**

**ESBRIET ORAL CAPSULE, ESBRIET ORAL TABLET 267 MG, 801 MG**

**Exclusion Criteria**

**Required Medical Information**

The patient has a diagnosis of idiopathic pulmonary fibrosis confirmed by a high resolution CT scan or biopsy AND the patient does not have evidence or suspicion of an alternative interstitial lung disease diagnosis AND liver function tests have been performed prior to start of therapy

**Age Restriction**

**Prescriber Restriction**

Prescribed by or in consultation with a pulmonologist

**Coverage Duration**

Through benefit year

**Other Criteria**

For renewal, patient experienced stabilization from baseline or a less than 10 percent decline in force vital capacity AND the patient has not experienced AST or ALT elevations greater than 5 times the upper limit of normal or greater than 3 times the upper limit of normal with signs or symptoms of severe liver damage.

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## Evenity (Romosozumab)

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### Drugs

**EVENITY SUBCUTANEOUS SYRINGE 210MG/2.34ML ( 105MG/1.17MLX2)**

### Exclusion Criteria

#### Required Medical Information

Diagnosis of Osteoporosis in a postmenopausal female AND one or more of the following: 1) History of osteoporotic fracture, or 2) Documented trial and failure of bisphosphonate or 3) Documented contraindication or intolerance to bisphosphonate therapy. Patient has not received more than 1 year of therapy with Evenity.

### Age Restriction

### Prescriber Restriction

### Coverage Duration

12 months

### Other Criteria

### Indications

All FDA-approved Indications.

### Off Label Uses

**Drugs**  
**EVRYSDI**

**Exclusion Criteria**

**Required Medical Information**

Diagnosis of spinal muscular atrophy.

**Age Restriction**

Patients 2 months and older

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**

*deferasirox oral tablet, dispersible*

**Exclusion Criteria**

Creatinine clearance less than 40 mL/minute. Platelet count less than 50 x 10<sup>9</sup>/L. Poor performance status. Severe (Child-Pugh class C) hepatic impairment. High-risk myelodysplastic syndromes. Advanced malignancies. Gastrointestinal ulceration or hemorrhage.

**Required Medical Information****Age Restriction**

2 years of age or older for chronic iron overload due to transfusions. 10 years of age or older for chronic iron overload due to NTDT.

**Prescriber Restriction****Coverage Duration**

3 months

**Other Criteria****Indications**

All FDA-approved Indications.

**Off Label Uses**

## FANAPT (iloperidone)

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### Drugs

FANAPT ORAL TABLET, FANAPT ORAL TABLETS,DOSE PACK

### Exclusion Criteria

#### Required Medical Information

Documented trial of any of the two following drugs: aripiprazole, clozapine, olanzapine, risperidone, quetiapine, ziprasidone

### Age Restriction

### Prescriber Restriction

### Coverage Duration

Through end of benefit year.

### Other Criteria

### Indications

All FDA-approved Indications.

### Off Label Uses

**Drugs**  
**FARYDAK**

**Exclusion Criteria**

**Required Medical Information**

Clinically diagnosed with multiple myeloma. Trial and failure of at least two prior treatment regimens, including bortezomib and an immunomodulatory agent. Must be used in combination with bortezomib and dexamethasone.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**FASENRA, FASENRA PEN**

**Exclusion Criteria**

**Required Medical Information**

Documentation that the patient has asthma with an eosinophilic phenotype defined as blood eosinophils greater than or equal to 300 cells/ $\mu$ L within previous 12 months or greater than or equal to 150 cells/ $\mu$ L within 6 weeks of dosing AND medication will be used in combination with a corticosteroid inhaler and long acting beta2-agonist AND Patient must have experienced two or more exacerbations in the previous year OR require daily oral corticosteroids

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

6 months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**



**Drugs**

*clozapine oral tablet, disintegrating*

**Exclusion Criteria**

If the patient has any of the following contraindications: agranulocytosis, bone marrow suppression, coma, ileus, leukopenia, myocarditis or neutropenia, OR if the patient has CNS depression, dementia-related psychosis or uncontrolled epilepsy.

**Required Medical Information**

A statement showing the patient is unwilling or unable to take tablets or capsules orally or at high risk for non-compliance AND is not receiving other tablets or capsules indicating that the patient can take non-dissolvable tablets.

**Age Restriction**

**Prescriber Restriction**

Part of a clozapine registry.

**Coverage Duration**

Through end of benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## FENTANYL CITRATE BUCCAL

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### **Drugs**

*fentanyl citrate buccal lozenge on a handle*

### **Exclusion Criteria**

Management of acute or post-operative pain, including headache/migraine, dental pain, or use in the emergency room.  
Opioid non-tolerant patients.

### **Required Medical Information**

Diagnosis of cancer AND 1. Use is for breakthrough cancer pain, AND 2. Patient is opioid tolerant and taking at least 60 mg morphine/day, at least 25 mcg transdermal fentanyl/hour, at least 30 mg of oxycodone daily, at least 8 mg oral hydromorphone daily or an equianalgesic dose of another opioid for a week or longer, AND 3. At least TWO other formulary short-acting strong narcotic analgesic alternatives (e.g. hydrocodone/acetaminophen, hydromorphone, morphine, oxycodone, oxycodone/acetaminophen) have been ineffective, not tolerated, or contraindicated, AND 4. Prescriber is registered in the Transmucosal Immediate Release Fentanyl (TIRF) Risk Evaluation and Mitigation Strategy Access program.

### **Age Restriction**

16 years or older

### **Prescriber Restriction**

Prescribed by an oncologist or pain specialist.

### **Coverage Duration**

3 months

### **Other Criteria**

### **Indications**

All FDA-approved Indications.

### **Off Label Uses**

**Drugs**  
**FERRIPROX ORAL TABLET**

**Exclusion Criteria**

**Required Medical Information**

Diagnosis of transfusional iron overload due to thalassemia syndromes AND patient has failed prior chelation therapy with Desferal or Exjade (failure is defined as a serum ferritin level greater than 2,500 mcg/L) or patient has a contraindication or intolerance to Desferal or Exjade AND Patient has an absolute neutrophil count greater than  $1.5 \times 10^9/L$ .

**Age Restriction**

**Prescriber Restriction**

Prescribed by a hematologist/oncologist or hepatologist

**Coverage Duration**

Through benefit year

**Other Criteria**

For renewal, patient has experienced at least a 20% reduction in serum ferritin levels and has an absolute neutrophil count greater than  $0.5 \times 10^9/L$

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**FETZIMA**

**Exclusion Criteria**

**Required Medical Information**

Documented trial of any two generic antidepressants (e.g. bupropion, citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, paroxetine CR, sertraline, duloxetine, venlafaxine).

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year,

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**FINTEPLA**

**Exclusion Criteria**

**Required Medical Information**

Patients had a clinical diagnosis of Dravet syndrome and seizures that were inadequately controlled on at least 1 antiepileptic drug (AED) OR treatment including vagal nerve stimulation OR ketogenic diet.

**Age Restriction**

Children 2 and older

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
*icatibant*

**Exclusion Criteria**

**Required Medical Information**

Documentation of clinical diagnosis of hereditary angioedema or C1 inhibitor deficiency and having angioedema attacks.

**Age Restriction**

**Prescriber Restriction**

Must be prescribed by an allergist, immunologist, hematologist, or a physician that specializes in the treatment of HAE or related disorders.

**Coverage Duration**

3 months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## Firdapse (Amidampridine)

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### **Drugs** **FIRDAPSE**

#### **Exclusion Criteria**

Member has a history of seizures

#### **Required Medical Information**

The diagnosis has been confirmed by one of the following: A) Presence of anti-P/Q-type voltage-gated calcium channel (VGCC) antibodies OR B) Characteristic electromyography (EMG).

#### **Age Restriction**

#### **Prescriber Restriction**

Neurologist

#### **Coverage Duration**

Through the benefit year

#### **Other Criteria**

#### **Indications**

All FDA-approved Indications.

#### **Off Label Uses**

**Drugs  
FORTEO**

**Exclusion Criteria**

Because of an increased incidence of osteosarcoma, Forteo should not be prescribed for patients who are at increased baseline risk for osteosarcoma (including those with Paget's disease of bone or unexplained elevations of alkaline phosphatase, open epiphyses, or prior radiation therapy involving the skeleton).

**Required Medical Information**

Diagnosis of one of the following: A) Osteoporosis in a postmenopausal female, or B) Primary or hypogonadal osteoporosis in a male, or C) Osteoporosis associated with sustained systemic glucocorticoid therapy AND one or more of the following: 1) History of osteoporotic fracture, or 2) Documented trial and failure of bisphosphonate and Prolia, or 3) Documented contraindication or intolerance to bisphosphonate therapy and Prolia. Patient has not received more than 2 years of therapy with Forteo.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Initial: 1 year. Renewal: 1 year not to exceed 2 years of total therapy.

**Other Criteria**

Treatment failure is defined as documented continued bone loss after at least three months despite treatment with a bisphosphonate or Prolia. Note: Since the effects of long-term treatment with Forteo are not known at this time, therapy for more than 2 years duration is considered experimental and investigational.

**Indications**

All FDA-approved Indications.

**Off Label Uses**



**Drugs**

FYCOMPA ORAL SUSPENSION, FYCOMPA ORAL TABLET 10 MG, 12 MG, 2 MG, 4 MG, 6 MG, 8 MG

**Exclusion Criteria**

**Required Medical Information**

Documented diagnosis of partial-onset seizure or primary generalized tonic-clonic seizures AND treatment failure of at least two other formulary medications used in the treatment of provided diagnosis.

**Age Restriction**

4 years of age and older

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**GARDASIL 9 (PF)**

**Exclusion Criteria**

**Required Medical Information**

Patient age

**Age Restriction**

Must be between 9 and 45 years of age

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

Dosing 0.5 ml/dose IM. Give the first dose at an elected date, the second dose 2 months after the first, and the third dose 6 months after the first dose. The vaccine is not intended to be used for treatment of active external genital lesions. cervical, vulvar, vaginal, and anal cancers. CIN. VIN. VaIN. or AIN.

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**GATTEX 30-VIAL**

**Exclusion Criteria**

Active gastrointestinal malignancy (gastrointestinal tract, hepatobiliary, pancreatic), colorectal cancer, or small bowel cancer

**Required Medical Information**

Diagnosis of short bowel syndrome AND patient is receiving specialized nutritional support (i.e. parenteral nutrition)

**Age Restriction**

1 years of age or older

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

For renewal, patient has a reduced need for parenteral support (20% reduction) after at least 6 months of therapy.

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**GAVRETO**

**Exclusion Criteria**

**Required Medical Information**

Diagnosis of Non-small cell lung cancer, metastatic, RET fusion-positive.

**Age Restriction**

**Prescriber Restriction**

Oncology

**Coverage Duration**

Through end of benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**

**GILENYA ORAL CAPSULE 0.5 MG**

**Exclusion Criteria**

Recent (within the last 6 months) occurrence of: myocardial infarction, unstable angina, stroke, transient ischemic attack, decompensated heart failure requiring hospitalization, or Class III/IV heart failure. History or presence of Mobitz Type II 2nd degree or 3rd degree AV block or sick sinus syndrome, unless patient has a pacemaker. Baseline QTc interval greater than or equal to 500 ms. Receiving concurrent treatment with Class Ia or Class III anti-arrhythmic drugs (quinidine, procainamide, amiodarone, sotalol). Treatment of primary progressive MS is not covered. Combination therapy with a beta interferon product, Gilenya, Aubagio, Tecfidera, Tysabri or Copaxone is not covered.

**Required Medical Information**

Diagnosis of a relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease OR diagnosis of first clinical episode with MRI features consistent with MS AND Patient will be observed for signs and symptoms of bradycardia in a controlled setting for at least 6 hours after the first dose.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**GILOTRIF**

**Exclusion Criteria**

**Required Medical Information**

Documented diagnosis of 1) Metastatic non-small cell lung cancer (NSCLC) with tumors that have non-resistant epidermal growth factor receptor (EGFR) mutations as detected by an FDA-approved test OR 2) Metastatic squamous non-small cell lung cancer progressing after platinum-based chemotherapy.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**GIMOTI**

**Exclusion Criteria**

**Required Medical Information**

Diagnosis of acute OR recurrent diabetic gastroparesis.

**Age Restriction**

18 years or older

**Prescriber Restriction**

To not be used more than 12 weeks because of risk of side effects.

**Coverage Duration**

12 weeks of continuous use.

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## GLEEVEC (imatinib mesylate)

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### Drugs

*imatinib oral tablet 100 mg, 400 mg*

### Exclusion Criteria

#### Required Medical Information

Diagnosis of one of the following: A) Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML), or B) Ph+ acute lymphoblastic leukemia (ALL), or C) Gastrointestinal tumor (GIST) where patient has documented c-KIT (CD117) positive unresectable or metastatic malignant GIST or patient had resection of c-KIT positive GIST and imatinib will be used as an adjuvant therapy, or D) Dermatofibrosarcoma protuberans that is unresectable, recurrent, or metastatic, or E) Hypereosinophilic syndrome or chronic eosinophilic leukemia, or F) Myelodysplastic syndrome or myeloproliferative disease associated with platelet-derived growth factor receptor gene re-arrangements, or G) Aggressive systemic mastocytosis without the D816V c-KIT mutation or with c-KIT mutation or with c-KIT mutational status unknown.

#### Age Restriction

1 year of age or older - newly diagnosed CML in the chronic phase or newly diagnosed Ph+ ALL. 18 years of age or older for other indications.

#### Prescriber Restriction

#### Coverage Duration

Through end of benefit year

#### Other Criteria

#### Indications

All FDA-approved Indications.

#### Off Label Uses



## HETLIOZ

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### **Drugs** **HETLIOZ**

#### **Exclusion Criteria**

#### **Required Medical Information**

Documented diagnosis of non-24-hour sleep-wake disorder (non-24) AND member is totally blind.

#### **Age Restriction**

18 years of age and older

#### **Prescriber Restriction**

#### **Coverage Duration**

Through end of benefit year

#### **Other Criteria**

#### **Indications**

All FDA-approved Indications.

#### **Off Label Uses**

## HRM - ANTI-ARRHYTHMICS

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### **Drugs**

*disopyramide phosphate oral capsule*

### **Exclusion Criteria**

#### **Required Medical Information**

The drug is being prescribed for an FDA-approved indication

#### **Age Restriction**

PA applies to patients 65 years or older.

#### **Prescriber Restriction**

#### **Coverage Duration**

Through end of benefit year

#### **Other Criteria**

#### **Indications**

All FDA-approved Indications.

#### **Off Label Uses**

## HRM - ANTIHISTAMINES

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### Drugs

*clemastine oral tablet 2.68 mg, cyproheptadine oral tablet, hydroxyzine HCl oral solution 10 mg/5 mL, promethazine oral, promethazine rectal suppository 12.5 mg, 25 mg, **PROMETHEGAN RECTAL SUPPOSITORY 25 MG, 50 MG***

### Exclusion Criteria

#### Required Medical Information

The drug is being prescribed for an FDA-approved indication

#### Age Restriction

PA applies to patients 65 years or older

#### Prescriber Restriction

#### Coverage Duration

Through end of benefit year

#### Other Criteria

#### Indications

All FDA-approved Indications.

#### Off Label Uses

**Drugs**

*trihexyphenidyl*

**Exclusion Criteria**

**Required Medical Information**

The drug is being prescribed for an FDA-approved indication

**Age Restriction**

PA applies to patients 65 years or older

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## HRM - ANTIPSYCHOTICS

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### **Drugs**

*thioridazine*

### **Exclusion Criteria**

#### **Required Medical Information**

The drug is being prescribed for an FDA-approved indication AND the patient has tried and failed at least one non-HRM alternative (listed in OTHER CRITERIA).

#### **Age Restriction**

PA applies to patients 65 years or older

#### **Prescriber Restriction**

#### **Coverage Duration**

Through end of benefit year

#### **Other Criteria**

Applies to New Starts only. Non-HRM alternatives include: quetiapine, risperidone, aripiprazole, asenapine, olanzapine, ziprasidone

#### **Indications**

All FDA-approved Indications.

#### **Off Label Uses**

**Drugs**

*phenobarbital*

**Exclusion Criteria**

**Required Medical Information**

Verify the medication is being used for an FDA-approved diagnosis.

**Age Restriction**

PA applies to patients 65 years and older.

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## HRM - CALCIUM CHANNEL BLOCKERS, DIHYDROPYRIDINE

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### **Drugs**

*nifedipine oral capsule*

### **Exclusion Criteria**

#### **Required Medical Information**

The drug is being prescribed for an FDA-approved indication AND the patient has tried and failed at least one non-HRM alternative (listed in OTHER CRITERIA).

#### **Age Restriction**

PA applies to patients 65 years or older

#### **Prescriber Restriction**

#### **Coverage Duration**

Through end of benefit year

#### **Other Criteria**

Non-HRM alternatives include: extended-release nifedipine, nicardipine, amlodipine

#### **Indications**

All FDA-approved Indications.

#### **Off Label Uses**

**Drugs**

*meprobamate*

**Exclusion Criteria**

**Required Medical Information**

The drug is being prescribed for an FDA-approved indication.

**Age Restriction**

PA applies to patients 65 years or older

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**



**Drugs**

**DUAVEE**, *estradiol-norethindrone acet oral tablet 1-0.5 mg*, **MENEST ORAL TABLET 0.3 MG, 0.625 MG, 1.25 MG**, **PREMARIN ORAL, PREMPHASE, PREMPRO**

**Exclusion Criteria**

**Required Medical Information**

Medical documentation of FDA-approved indication, AND trial and failure or contraindication to two preferred alternatives for established indication. Preferred alternatives include: Vasomotor symptoms of menopause: requires provider acknowledgement of HRM status, Vulvar or vaginal atrophy: Premarin cream, Osteoporosis: alendronate, ibandronate, raloxifene.

**Age Restriction**

PA applies to patients 65 years or older

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## HRM - PLATELET INHIBITORS

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### **Drugs**

*dipyridamole oral*

### **Exclusion Criteria**

#### **Required Medical Information**

The drug is being prescribed for an FDA-approved indication AND the patient has tried and failed at least one non-HRM alternative (listed in OTHER CRITERIA).

#### **Age Restriction**

PA applies to patients 65 years or older

#### **Prescriber Restriction**

#### **Coverage Duration**

Through end of benefit year

#### **Other Criteria**

A trial and failure of clopidogrel is required prior to approval of dipyridamole.

#### **Indications**

All FDA-approved Indications.

#### **Off Label Uses**

## HRM - TERTIARY TCAs

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### Drugs

*doxepin oral capsule 10 mg, 100 mg, 150 mg, 25 mg, 50 mg, 75 mg, doxepin oral concentrate 10 mg/mL, perphenazine-amitriptyline*

### Exclusion Criteria

#### Required Medical Information

The drug is being prescribed for an FDA-approved indication AND the patient has tried and failed at least one non-HRM alternative (listed in OTHER CRITERIA).

#### Age Restriction

PA applies to patients 65 years or older

#### Prescriber Restriction

#### Coverage Duration

Through end of benefit year

#### Other Criteria

Applies to New Starts only. Non-HRM alternatives include: nortriptyline, desipramine, trazodone, SSRIs (fluoxetine, paroxetine, citalopram, escitalopram), SNRIs (venlafaxine, duloxetine), mirtazapine, bupropion.

#### Indications

All FDA-approved Indications.

#### Off Label Uses

**Drugs**

**HUMIRA PEN, HUMIRA PEN CROHNS-UC-HS START, HUMIRA PEN PSOR-UEVITS-ADOL HS, HUMIRA SUBCUTANEOUS SYRINGE KIT 40 MG/0.8 ML, HUMIRA(CF) PEN CROHNS-UC-HS, HUMIRA(CF) PEN PSOR-UV-ADOL HS, HUMIRA(CF) PEN SUBCUTANEOUS PEN INJECTOR KIT 40 MG/0.4 ML, 80 MG/0.8 ML, HUMIRA(CF) SUBCUTANEOUS SYRINGE KIT 10 MG/0.1 ML, 20 MG/0.2 ML, 40 MG/0.4 ML**

**Exclusion Criteria****Required Medical Information**

Diagnosis of 1 of the following: A) Mod-severe rheumatoid arthritis and trial of 1 or more non-biologic disease modifying anti-rheumatic drugs (DMARD) (e.g., hydroxychloroquine [HCQ], sulfasalazine, methotrexate [MTX], leflunomide, azathioprine, cyclosporine) for at least 3 months, or B) Mod-severe polyarticular juvenile idiopathic arthritis (JIA) and trial of 1 or more non-biologic DMARDs (e.g., HCQ, sulfasalazine, MTX, leflunomide, azathioprine, cyclosporine) for at least 3 months, or C) Psoriatic arthritis and trial of MTX, or D) Ankylosing spondylitis and trial of 1 or more NSAIDs, or E) Mod-severe chronic plaque psoriasis (affecting more than 5% of body surface area or crucial body areas such as the hands, feet, face, or genitals) and trial of at least 1 of the following: phototherapy (including but not limited to Ultraviolet A with a psoralen [PUVA] and/or retinoids [RePUVA] for at least 1 continuous month or 1 or more oral systemic treatments (e.g., MTX, cyclosporine, acitretin, sulfasalazine) for at least 3 months, or F) Mod-severe Crohn's disease and trial of 2 or more of the following: corticosteroids (e.g., prednisone, methylprednisolone) or non-biologic DMARDs (e.g., azathioprine, MTX, mercaptopurine), or G) Mod-severe ulcerative colitis trial of 2 or more of the following: corticosteroids (e.g., prednisone, methylprednisolone), 5-ASA (i.e. mesalamine, sulfasalazine, balsalazide, olsalazine) or non-biologic DMARDs (azathioprine, MTX, mercaptopurine), or H) Hidradenitis suppurativa, or I) Non-infectious intermediate, posterior, and panuveitis and trial of 1 or more of the following: periocular, intraocular, or systemic corticosteroids, immunosuppressants (azathioprine, MTX, mycophenolate mofetil, cyclophosphamide, cyclosporine). A trial is defined as an inadequate response, intolerance or contraindication to the therapy.

**Age Restriction**

2 years of age or older for JIA or uveitis. 6 years of age and older for pediatric Crohn's disease. 12 years of age or older for hidradenitis suppurativa. 18 years of age or older for all other indications.

**Prescriber Restriction****Coverage Duration**

Through end of benefit year

**Other Criteria****Indications**

All FDA-approved Indications.

**Off Label Uses**

## IBRANCE

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### Drugs IBRANCE

#### Exclusion Criteria

#### Required Medical Information

Diagnosis of HR-positive, HER2-negative advanced or metastatic breast cancer in combination with: 1)an aromatase inhibitor as initial endocrine based therapy in postmenopausal women OR 2)fulvestrant in women with disease progression following endocrine therapy OR 3) an aromatase inhibitor in men with advanced or metastatic breast cancer.

#### Age Restriction

#### Prescriber Restriction

#### Coverage Duration

Through benefit year

#### Other Criteria

#### Indications

All FDA-approved Indications.

#### Off Label Uses

**Drugs**

**ICLUSIG ORAL TABLET 15 MG, 45 MG**

**Exclusion Criteria**

**Required Medical Information**

Diagnosis of one of the following: A) Chronic myelogenous leukemia (CML) and patient has tried and failed or has an intolerance to two first-line tyrosine kinase inhibitors OR patient has a known T315I mutation, or B) Philadelphia chromosome-positive acute lymphoblastic leukemia and the patient has tried and failed or had an intolerance to two previous tyrosine kinase inhibitors OR patient has a known T315I mutation.

**Age Restriction**

18 years or older

**Prescriber Restriction**

Prescribed by a hematologist/oncologist

**Coverage Duration**

3 Months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## Iclusig (ponatinib)

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### Drugs

ICLUSIG ORAL TABLET 10 MG, 30 MG

### Exclusion Criteria

#### Required Medical Information

Documented diagnosis of one of the following: 1. T315I-positive chronic myeloid leukemia (CML)OR 2. T315I-positive Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL)OR 3. Chronic phase (CP) chronic myeloid leukemia (CML)with resistance or intolerance to at least two prior tyrosine kinase inhibitors OR 4. Accelerated phase (AP) or blast phase (BP) chronic myeloid leukemia (CML)AND no other tyrosine kinase (TKI) therapy is indicated OR 5. Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL)AND no other tyrosine kinase (TKI) therapy is indicated

#### Age Restriction

18 years of age or older

#### Prescriber Restriction

Prescribed by an oncologist or hematologist

#### Coverage Duration

3 months

#### Other Criteria

#### Indications

All FDA-approved Indications.

#### Off Label Uses

**Drugs**  
**IDHIFA**

**Exclusion Criteria**

**Required Medical Information**

1. Diagnosis of relapsed or refractory acute myeloid leukemia (AML) with an isocitrate dehydrogenase-2 (IDH2) mutation  
AND 2. Prescriber agrees to monitor for signs and symptoms of differentiation syndrome.

**Age Restriction**

**Prescriber Restriction**

Oncologist or Hematologist

**Coverage Duration**

Through the end of benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**



**Drugs**

**IMBRUVICA ORAL CAPSULE 140 MG, 70 MG, IMBRUVICA ORAL TABLET**

**Exclusion Criteria**

**Required Medical Information**

Documented diagnosis of 1) Mantle Cell Lymphoma and has received at least one prior therapy, OR 2) chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL), OR 3) Waldenström's macroglobulinemia, OR 4) marginal zone lymphoma (MZL) and have received at least one prior anti-CD20-based therapy, OR 5) chronic graft-versus-host disease (cGVHD) after failure of one or more lines of systemic therapy.

**Age Restriction**

18 years of age and older

**Prescriber Restriction**

**Coverage Duration**

3 Months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**

**INBRIJA INHALATION CAPSULE, W/INHALATION DEVICE**

**Exclusion Criteria**

patient is not currently taking or has recently (within 2 weeks) taken a nonselective monoamine oxidase (MAO) inhibitor (e.g., phenelzine and tranylcypromine)

**Required Medical Information**

Patient is currently treated with carbidopa/levodopa AND is experiencing intermittent OFF episodes secondary to Parkinson's disease

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

3 months

**Other Criteria**

Reauthorization requires physician attestation of medications efficacy

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**INCRELEX**

**Exclusion Criteria**

Closed epiphyses. Active or suspected malignancy.

**Required Medical Information**

Diagnosis of one of the following: A) Severe primary IGF-1 deficiency, defined as height standard deviation score (SDS) less than or equal to -3.0 AND basal IGF-1 SDS less than or equal to -3.0 AND normal or elevated growth hormone, or B) Growth hormone deletion with development of neutralizing antibodies to growth hormone AND other causes of IGF-1 deficiency (e.g., hypothyroidism, nutritional deficiencies, pituitary disorders, etc.) have been ruled out or corrected prior to initiating therapy.

**Age Restriction**

**Prescriber Restriction**

Pediatric endocrinologist

**Coverage Duration**

6 months to 1 year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**

**INGREZZA, INGREZZA INITIATION PACK**

**Exclusion Criteria**

**Required Medical Information**

Clinical documentation of FDA indication for treatment.

**Age Restriction**

18 years of age and older

**Prescriber Restriction**

**Coverage Duration**

Through the end of the benefit year.

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**

**INLYTA ORAL TABLET 1 MG, 5 MG**

**Exclusion Criteria**

**Required Medical Information**

Diagnosis of 1) advanced renal cell carcinoma AND patient failed one or more systemic therapies for renal cell carcinoma (e.g., sunitinib-, bevacizumab-, temsirolimus-, or cytokine-containing regimens) OR 2) advanced renal cell carcinoma and the medication will be used in combination with avelumab OR 3) advanced renal cell carcinoma (RCC) and the medication will be used in combination with pembrolizumab.

**Age Restriction**

18 years of age or older

**Prescriber Restriction**

**Coverage Duration**

3 months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**INQOVI**

**Exclusion Criteria**

**Required Medical Information**

Required diagnosis of Myelodysplastic syndrome, Previously treated and untreated, de novo and secondary, with the following French-American-British subtypes (refractory anemia, refractory anemia with ringed sideroblasts, refractory anemia with excess blasts, and chronic myelomonocytic leukemia and intermediate-1, intermediate-2, and high-risk International Prognostic Scoring System groups)

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**INREBIC**

**Exclusion Criteria**

Patients on treatment with ruxolitinib before initiation must taper and discontinue according to ruxolitinib prescribing information

**Required Medical Information**

Must provide labs showing patient is not thiamine deficient before starting drug

**Age Restriction**

18 years of age and older

**Prescriber Restriction**

Oncologist or Hematologist

**Coverage Duration**

3 months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**

**INTRON A INJECTION RECON SOLN 18 MILLION UNIT (1 ML), 50 MILLION UNIT (1 ML)**

**Exclusion Criteria**

**Required Medical Information**

Type B viral Hepatitis (HBeAg positive): Serum HBsAg positive for at least six months, AND elevated serum ALT 2 times ULN or moderate to severe hepatitis or fibrosis on biopsy. Type B Viral Hepatitis (HBeAg negative) HBsAG positive for at least 6 months AND BHV DNA level of 2000 IU/ml or more than 11,200 copies/ml AND One of the following, persistent ALT 2 times UNL or moderate to severe hepatitis or fibrosis on biopsy. Documentation must be provided showing trial and failure to our preferred agent Peg-Intron. Chronic Hepatitis C: Positive HCV antibody and HCV RNA. Documentation must be provided showing trial and failure to our preferred agent Peg-Intron. Condyloma Acuminatum or Perianal Warts: Must have documentation of trial and failure to preferred alternative or intolerance/contraindication to preferred alternatives. For external perianal warts, condylox gel, for external genital warts, podofilox, or imiquimod. Hairy Cell Leukemia: Medical documentation indicating diagnosis. Malignant Melanoma: Indicated as adjuvant to surgical treatment with malignant melanoma who are free of disease but at high risk for systemic recurrence, within 56 days of surgery. Follicular Lymphoma: Indicated for the initial treatment of clinically aggressive follicular Non-Hodgkins Lymphoma in conjunction with anthracycline-containing combination chemotherapy. Efficacy in patients with low-grade, low-tumor burden follicular Non-Hodgkins Lymphoma has not been demonstrated. AIDS-Related Kaposi Sarcoma: Indicated for the treatment of selected patients. The likelihood of response to therapy is greater in patients who are without systemic symptoms, who have limited lymphadenopathy and who have a relatively intact immune system as indicated by total CD4 count.

**Age Restriction**

For Hepatitis B- age 1 or older, For Hepatitis C - age 3 or older, All other diagnoses- 18 years or older.

**Prescriber Restriction**

**Coverage Duration**

1 year

**Other Criteria**

Medication is eligible for B vs. D determination

**Indications**

All FDA-approved Indications.

**Off Label Uses**



## INVEGA

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### Drugs

**INVEGA SUSTENNA INTRAMUSCULAR SYRINGE 117 MG/0.75 ML, 156 MG/ML, 234 MG/1.5 ML, 39 MG/0.25 ML, 78 MG/0.5 ML**, *paliperidone oral tablet extended release 24hr 1.5 mg, 3 mg, 6 mg, 9 mg*

### Exclusion Criteria

#### Required Medical Information

Diagnosis of Schizophrenia OR Schizoaffective Disorder AND documented treatment failure or intolerable side effects from treatment with two formulary antipsychotic medications such as risperidone, ziprasidone, quetiapine.

### Age Restriction

### Prescriber Restriction

### Coverage Duration

Through end of benefit year

### Other Criteria

### Indications

All FDA-approved Indications.

### Off Label Uses

**Drugs**  
**IRESSA**

**Exclusion Criteria**

**Required Medical Information**

Clinically diagnosed with metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an FDA-approved test.

**Age Restriction**

18 years of age or older

**Prescriber Restriction**

Prescribed by an oncologist or a hematologist

**Coverage Duration**

Through end of benefit year.

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**

**ISTURISA ORAL TABLET 1 MG, 10 MG, 5 MG**

**Exclusion Criteria**

**Required Medical Information**

Diagnosis of Cushing disease: Treatment of Cushing disease in adults for whom pituitary surgery is not an option or has not been curative.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## ITRACONAZOLE

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### **Drugs**

*itraconazole oral capsule*

### **Exclusion Criteria**

### **Required Medical Information**

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

3 months

### **Other Criteria**

### **Indications**

All FDA-approved Indications.

### **Off Label Uses**

**Drugs**  
**JAKAFI**

**Exclusion Criteria**

**Required Medical Information**

Diagnosis of A) acute graft-versus-host disease (GVHD) OR B) polycythemia vera in adults who have had an inadequate response to or are intolerant of hydroxyurea OR C) intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia veramyelofibrosis and post-essential thrombocythemiamyelofibrosis AND lab work indicating a complete blood count and platelet count before initiating therapy AND recent lab work indicating complete blood count AND platelet count for a dosage adjustment. Lab work must indicate platelets are more than 50 x 10<sup>9</sup>/L and dose must be less than 50 mg per day. No dose increases will be approved within 4 weeks of therapy and not more frequently than every 2 weeks. If no spleen reduction or symptom improvement after 6 months then discontinue the drug.

**Age Restriction**

12 years or older

**Prescriber Restriction**

**Coverage Duration**

3 months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs****JUXTAPID ORAL CAPSULE 10 MG, 20 MG, 30 MG, 5 MG****Exclusion Criteria**

Pregnancy. Concomitant administration of moderate or strong CYP3A4 inhibitors (e.g., clarithromycin, conivaptan, indinavir, itraconazole, ketoconazole, lopinalvir/ritonavir, mibefradil, nefazodone, nelfinavir, posaconazole, ritonavir, saquinavir, telithromycin, voriconazole, amprenavir, aprepitant, atazanavir, ciprofloxacin, crizotinib, darunavir/ritonavir, diltiazem, erythromycin, fluconazole, fosamprenavir, imatinib, verapamil, etc.). Moderate to severe liver impairment or active liver disease including unexplained persistent abnormal liver function tests. Dosage regimen above 60 mg per day.

**Required Medical Information**

Diagnosis of homozygous familial hypercholesterolemia as evidenced by one of the following: A) genetic confirmation of 2 mutant alleles at the LDL receptor, ApoB, PCSK9, or autosomal recessive hypercholesterolemia (ARH) adaptor protein gene locus OR B) untreated/pre-treatment LDL greater than 500 mg/dL with at least one of the following: 1) cutaneous or tendonous xanthoma before 10 years of age, OR 2) untreated LDL cholesterol levels consistent with heterozygous FH in both parents (greater than 190 mg/dL), AND Patient has tried and had an inadequate response to the maximum tolerated dose of a high potency statin (e.g., atorvastatin, rosuvastatin), unless statin contraindicated or statin intolerant, and a PCSK9 (e.g., Praluent, Repatha).

**Age Restriction**

18 years of age and older

**Prescriber Restriction**

Provider and patient must be registered in the Juxtapid REMS program

**Coverage Duration**

Initial: 6 months, Reauthorization: through benefit year

**Other Criteria****Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**

**JYNARQUE ORAL TABLETS, SEQUENTIAL**

**Exclusion Criteria**

**Required Medical Information**

Medication requested is being used to slow kidney function decline AND Liver function laboratory values (ALT, AST and bilirubin) have been reviewed and are appropriate before initiation.

**Age Restriction**

Patient is 18 years of age or older

**Prescriber Restriction**

**Coverage Duration**

Initial Authorization will be for 3 months. Reauthorization will be for 1 year.

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**

**KALYDECO ORAL GRANULES IN PACKET 25 MG, 50 MG, 75 MG, KALYDECO ORAL TABLET**

**Exclusion Criteria**

**Required Medical Information**

Medical documentation of cystic fibrosis AND member has one mutation in the CFTR gene that is responsive to ivacaftor based on clinical and/or in vitro assay data.

**Age Restriction**

Ivacaftor oral granules are approved in patients 6 months of age and older. Ivacaftor oral tablets are approved in patients 6 years of age and older.

**Prescriber Restriction**

Endocrinologist or Pulmonologist

**Coverage Duration**

Through end of benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**



**Drugs**  
**KESIMPTA PEN**

**Exclusion Criteria**

**Required Medical Information**

Diagnosis of relapsing forms of multiple sclerosis (clinically isolated syndrome, relapsing-remitting MS, progressive-relapsing MS, secondary-progressive MS, or active secondary-progressive disease).

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**

**KISQALI FEMARA CO-PACK ORAL TABLET 200 MG/DAY(200 MG X 1)-2.5 MG, 400 MG/DAY(200 MG X 2)-2.5 MG, 600 MG/DAY(200 MG X 3)-2.5 MG, KISQALI ORAL TABLET 200 MG/DAY (200 MG X 1), 400 MG/DAY (200 MG X 2), 600 MG/DAY (200 MG X 3)**

**Exclusion Criteria**

**Required Medical Information**

Documented diagnosis of: A) hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer AND the medication will be used in combination with an aromatase inhibitor as initial endocrine-based therapy, or B) hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer AND the patient is postmenopausal AND the medication will be used in combination with fulvestrant (only applies to single agent Kisqali).

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year.

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**KORLYM**

**Exclusion Criteria**

Pregnancy Category X and for patients who require concomitant treatment with systemic corticosteroids for serious medical conditions or illnesses (e.g., immunosuppression after organ transplantation).

**Required Medical Information**

Stated diagnosis to control hyperglycemia secondary to hypercortisolism in adult patients with endogenous Cushing's syndrome who have type 2 diabetes mellitus or glucose intolerance and have failed surgery or are not candidates for surgery. Korlym should not be used in the treatment of patients with type 2 diabetes unless it is secondary to Cushing's syndrome. Do not exceed 20 mg/kg per day.

**Age Restriction**

18 years and older

**Prescriber Restriction**

Endocrinologist

**Coverage Duration**

Through benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**KOSELUGO**

**Exclusion Criteria**

**Required Medical Information**

Documentation that the member has neurofibromatosis type 1 (NF1) who have symptomatic, inoperable plexiform neurofibromas (PN).

**Age Restriction**

**Prescriber Restriction**

Oncologist

**Coverage Duration**

3 months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**

**KUVAN ORAL TABLET,SOLUBLE**

**Exclusion Criteria**

**Required Medical Information**

Documented diagnosis of hyperphenylalaninemia (HPA) due to tetrahydrobiopterin- (BH4-) responsive Phenylketonuria (PKU).

**Age Restriction**

1 month and older

**Prescriber Restriction**

**Coverage Duration**

Initial: 2 months. Renewal: through end of benefit year

**Other Criteria**

For initial approval, Patient will have phenylalanine levels measured one week after starting therapy and periodically for up to two months of therapy to determine response. For renewal, patient has been determined to be a responder to therapy (i.e. phenylalanine levels have decreased by at least 30% from baseline) and phenylalanine levels will be measured periodically during therapy.

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## Kynmobi (apomorphine)

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### Drugs

KYNMOBI SUBLINGUAL FILM 10 MG, 15 MG, 20 MG, 25 MG, 30 MG

### Exclusion Criteria

#### Required Medical Information

Requires diagnosis of Parkinson's disease

### Age Restriction

#### Prescriber Restriction

Neurologist for initial prescription

#### Coverage Duration

Through end of benefit year

### Other Criteria

#### Indications

All FDA-approved Indications.

### Off Label Uses

### **Drugs** *lapatinib*

#### **Exclusion Criteria**

##### **Required Medical Information**

Diagnosis of breast cancer with tumors that overexpress human epidermal growth factor receptor 2 (HER2) AND 1. the medication will be used in combination with Xeloda in a patient with advanced or metastatic disease and the patient has received prior therapy including an anthracycline, a taxane, and trastuzumab, or 2) The medication will be used in combination with Femara for the treatment of a postmenopausal woman with hormone receptor-positive metastatic disease for whom hormonal therapy is indicated.

##### **Age Restriction**

18 years or older

##### **Prescriber Restriction**

Must be prescribed by Oncologist and Oncologist must monitor treatment

##### **Coverage Duration**

Initial: 3 months, Renewal: 6 months with documentation of continued benefit

##### **Other Criteria**

##### **Indications**

All FDA-approved Indications.

##### **Off Label Uses**

## LATUDA (lurasidone)

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### Drugs

LATUDA ORAL TABLET 120 MG, 20 MG, 40 MG, 60 MG, 80 MG

### Exclusion Criteria

#### Required Medical Information

Documented trial of any of the two following drugs: aripiprazole, clozapine, olanzapine, risperidone, quetiapine, ziprasidone

### Age Restriction

### Prescriber Restriction

### Coverage Duration

Through end of benefit year.

### Other Criteria

### Indications

All FDA-approved Indications.

### Off Label Uses



**Drugs**

*ledipasvir-sofosbuvir*

**Exclusion Criteria**

**Required Medical Information**

Provider must submit medical records documenting the following: 1) medical diagnosis of Chronic Hepatitis C with labs documenting genotype and subtype, AND 2) medical records documenting viral load taken within 6 months of beginning therapy, AND 3) fibrosis score to confirm appropriate duration of treatment, AND 4) documentation of previous HCV therapies to confirm appropriate duration of treatment.

**Age Restriction**

Patient must be 3 years of age or older

**Prescriber Restriction**

Prescribed by, a gastroenterologist, hepatologist, or infectious disease physician.

**Coverage Duration**

12 to 24 weeks based on the AASLD treatment guidelines

**Other Criteria**

Criteria and coverage durations will be applied consistent with current AASLD/IDSA guidance.

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**

LENVIMA ORAL CAPSULE 10 MG/DAY (10 MG X 1), 12 MG/DAY (4 MG X 3), 14 MG/DAY(10 MG X 1-4 MG X 1), 18 MG/DAY (10 MG X 1-4 MG X 2), 20 MG/DAY (10 MG X 2), 24 MG/DAY(10 MG X 2-4 MG X 1), 4 MG, 8 MG/DAY (4 MG X 2)

**Exclusion Criteria**

**Required Medical Information**

Documented diagnosis of: 1) locally recurrent or metastatic, progressive, radioactive iodine-refractory Differentiated Thyroid Cancer OR, 2) Advanced Renal Cell Carcinoma and medication will be used in combination with everolimus following one prior anti-angiogenic therapy, OR 3) unresectable hepatocellular carcinoma (HCC), OR 4) advanced endometrial carcinoma that is not microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR), who have disease progression following prior systemic therapy and are not candidates for curative surgery or radiation and the medication will be used for pembrolizumab.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Through benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**

*ambrisentan*

**Exclusion Criteria**

Known or suspected pregnancy.

**Required Medical Information**

Diagnosis of Pulmonary Arterial Hypertension (PAH) WHO Group 1 that was confirmed by right heart catheterization, AND Patient has WHO Functional Class II - IV symptoms, AND The patient has had a vasoreactivity test unless the provider indicates that the patient has a contraindication to the test or indicates clinical inappropriateness to the vasoreactivity test, AND Must have tried and failed or has a contraindication to the use of a calcium channel blocker if they have a positive vasoreactivity test. For women of child-bearing potential, approval requires a negative pregnancy test and documentation of two reliable methods of contraception OR have had a tubal sterilization OR a Copper T 380A IUD or LNG 20 IUD inserted.

**Age Restriction**

18 years and older

**Prescriber Restriction**

Prescribed by a pulmonologist, a cardiologist, or a physician specializing in pulmonary arterial hypertension.

**Coverage Duration**

3 months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs****LEUKINE INJECTION RECON SOLN****Exclusion Criteria**

Chemotherapy or radiotherapy within 24 hours or concomitantly, excess leukemic myeloid blasts in the bone marrow or blood (10% or greater), hypersensitivity to granulocyte-macrophage colony-stimulating factor (GM-CSF) or yeast-derived products, allergic or anaphylactoid reactions to the medication in the past.

**Required Medical Information**

Diagnosis of one of the following: A) Patient has undergone allogeneic or autologous bone marrow transplant (BMT) and engraftment is delayed or failed and patient does not have excessive leukemic myeloid blasts in bone marrow/peripheral blood (more than 10%), or B) Patient is undergoing autologous peripheral-blood progenitor cell transplant to mobilize progenitor cells for collection by leukapheresis, or C) Medication will be used for myeloid reconstitution after an autologous or allogeneic BMT, or D) Patient has acute myeloid leukemia and administration will be after completion of induction chemotherapy, or E) is being used to increase survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS]).

**Age Restriction****Prescriber Restriction**

Oncologist or Hematologist

**Coverage Duration**

Through end of benefit year

**Other Criteria**

This drug may be covered under Medicare Part B or D depending upon the circumstances. Information may need to be submitted describing the use and setting of the drug to make the determination. Home or LTC administration covered under Medicare Part D. Physician office or healthcare setting administration, redirect for Medicare Part B coverage.

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## LIDOCAINE PRODUCTS

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### **Drugs**

*lidocaine topical adhesive patch, medicated 5 %, lidocaine topical ointment*

### **Exclusion Criteria**

### **Required Medical Information**

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

Through end of benefit year

### **Other Criteria**

### **Indications**

All FDA-approved Indications.

### **Off Label Uses**

**Drugs**  
**LOKELMA**

**Exclusion Criteria**

**Required Medical Information**

Documentation of elevated serum potassium (greater than 5.0 mEq/L) and the beneficiary has failure, contraindication or intolerance to sodium polystyrene sulfonate oral suspension.

**Age Restriction**

18 years and older

**Prescriber Restriction**

**Coverage Duration**

6 months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**

**LONSURF ORAL TABLET 15-6.14 MG, 20-8.19 MG**

**Exclusion Criteria**

**Required Medical Information**

Documented diagnosis of 1) metastatic colorectal cancer previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy OR 2) metastatic gastric or gastroesophageal junction adenocarcinoma previously treated with at least two prior lines of chemotherapy that included a fluoropyrimidine, a platinum, either a taxane or irinotecan, and if appropriate, HER2/NEU-targeted therapy.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year.

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**

**LORBRENA ORAL TABLET 100 MG, 25 MG**

**Exclusion Criteria**

**Required Medical Information**

Documentation of anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) whose disease has progressed on one of the following: 1. crizotinib and at least one other ALK inhibitor for metastatic disease; or 2. alectinib as the first ALK inhibitor therapy for metastatic disease; or 3. ceritinib as the first ALK inhibitor therapy for metastatic disease.

**Age Restriction**

**Prescriber Restriction**

Oncology

**Coverage Duration**

3 months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**



**Drugs****LUPRON DEPOT, LUPRON DEPOT (3 MONTH), LUPRON DEPOT (4 MONTH), LUPRON DEPOT (6 MONTH)****Exclusion Criteria**

Pregnancy in patients with child-bearing potential. Breastfeeding. Undiagnosed abnormal vaginal bleeding.

**Required Medical Information**

Diagnosis of one of the following: A) Advanced or metastatic prostate cancer (7.5 mg 1-month, 22.5 mg 3-month, 30 mg 4-month, & 45 mg 6-month depots only), or B) Endometriosis (3.75 mg 1-month & 11.25 mg 3-month depots only) AND 1. For initial authorization, patient has had an inadequate pain control response or has an intolerance or contraindication to one of the following: Danazol or combination [estrogen/progesterone] oral contraceptives or progestins, or 2. For retreatment course, patient is experiencing recurrence of symptoms after an initial course of therapy with leuprolide acetate and norethindrone acetate 5 mg daily will be co-administered, or C) Anemia due to uterine Leiomyomata (Fibroids) (3.75 mg 1-month & 11.25 mg 3-month depots only) AND patient is preoperative, or D) Central precocious puberty (Lupron Depot-Ped) AND submission of pubertal gonadal sex steroid levels (testosterone greater than 30 ng/dL, estradiol greater than 20 pg/mL AND a pubertal LH increase upon native GnRH stimulation AND pelvic ultrasound assessment (girls) is required for approval along with notes indicating premature development of secondary sexual characteristics at or before the age of 8 yrs in girls and 9 yrs in boys and significant advancement of bone age and/or a poor adult height prediction AND other causes of sexual precocity must be excluded.

**Age Restriction****Prescriber Restriction**

Oncologist, Endocrinologist, Urologist, or Gynecologist to prescribe

**Coverage Duration**

Prostate cancer: through benefit year, Uterine Leiomyoma: 3 months, All other indications: 6 months

**Other Criteria**

For endometriosis and uterine fibroids, patient will be using nonhormonal contraception during and for 12 weeks after therapy.

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**LYNPARZA ORAL TABLET**

**Exclusion Criteria**

**Required Medical Information**

Documentation of 1) BRCA-mutated advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy OR 2) HRD-positive advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy OR 3) recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in complete or partial response to platinum-based chemotherapy OR 4) BRCA-mutated (gBRCAm) advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy OR 5) BRCA-mutated HER2-negative Metastatic Breast Cancer OR 6) BRCA-mutated Metastatic Pancreatic Adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen OR 7) HRR Gene-mutated Metastatic Castration-Resistant Prostate Cancer which has progressed following prior treatment with enzalutamide or abiraterone.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## Mavenclad (Cladribine)

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### Drugs

MAVENCLAD (10 TABLET PACK), MAVENCLAD (4 TABLET PACK), MAVENCLAD (5 TABLET PACK), MAVENCLAD (6 TABLET PACK), MAVENCLAD (7 TABLET PACK), MAVENCLAD (8 TABLET PACK), MAVENCLAD (9 TABLET PACK)

### Exclusion Criteria

Individual with current malignancy OR human immunodeficiency virus (HIV) infection OR an active chronic infection (e.g., hepatitis or tuberculosis)

### Required Medical Information

Documentation of diagnosis of relapsing multiple sclerosis, including relapsing-remitting disease or active secondary progressive disease AND the patient has had a trial and inadequate response or intolerance to at least one alternative drug indicated for the treatment of multiple sclerosis.

### Age Restriction

### Prescriber Restriction

### Coverage Duration

1 year

### Other Criteria

Will only be approved for 2 treatment cycles.

### Indications

All FDA-approved Indications.

### Off Label Uses

**Drugs**  
**MAVYRET**

**Exclusion Criteria**

**Required Medical Information**

Provider must submit medical records documenting the following: 1) medical diagnosis of Chronic Hepatitis C with labs documenting genotype and subtype, AND 2) medical records documenting viral load taken within 6 months of beginning therapy, AND 3) fibrosis score to confirm appropriate duration of treatment, AND 4) documentation of previous HCV therapies to confirm appropriate duration of treatment. Authorization for retreatment requires the following: 1) Evidence of failure to achieve a sustained virologic response (SVR) or lack of efficacy during treatment (polymerase chain reaction (PCR) assay, 12 or more weeks after completing treatment or a 10-fold increase of viral load at week 6 of treatment) OR evidence of adverse event that required therapy discontinuation (Laboratory results and/or clinical presentation).

**Age Restriction**

**Prescriber Restriction**

Prescribed by, a gastroenterologist, hepatologist, or infectious disease physician.

**Coverage Duration**

based on the AASLD treatment guidelines

**Other Criteria**

Criteria and coverage durations will be applied consistent with current AASLD/IDSA guidance.

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## MEKINIST

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### Drugs

**MEKINIST ORAL TABLET 0.5 MG, 2 MG**

### Exclusion Criteria

#### Required Medical Information

Diagnosis of unresectable or metastatic melanoma, positive BRAF V600E or V600K mutation as detected by an FDA-approved test (THxID-BRAF Kit) or Clinical Laboratory Improvement Amendments (CLIA)-approved facility, and the patient has not received prior BRAF-inhibitor therapy.

#### Age Restriction

18 years or older

#### Prescriber Restriction

Oncologist

#### Coverage Duration

3 months

#### Other Criteria

#### Indications

All FDA-approved Indications.

#### Off Label Uses

**Drugs**  
**MEKTOVI**

**Exclusion Criteria**

**Required Medical Information**

Documentation of unresectable or metastatic melanoma with a BRAF V600E or V600K mutation, as detected by an FDA-approved test and that Mektovi will be used in combination with encorafenib.

**Age Restriction**

**Prescriber Restriction**

Oncology

**Coverage Duration**

3 months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## Metyrosine

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### Drugs

*metyrosine*

### Exclusion Criteria

#### Required Medical Information

Statement of diagnosis. Must have surgical resection planned, have a contraindication to surgery, or have malignant pheochromocytoma. For reauthorization: must have chart documentation from prescriber indicating improvement in condition.

### Age Restriction

### Prescriber Restriction

### Coverage Duration

Initial: 3 months, Renewal:through end of benefit year.

### Other Criteria

### Indications

All FDA-approved Indications.

### Off Label Uses

## MOLINDONE

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**Drugs**  
*molindone*

**Exclusion Criteria**

**Required Medical Information**

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**  
Through end of benefit year.

**Other Criteria**

**Indications**  
All FDA-approved Indications.

**Off Label Uses**



**Drugs**  
**NATPARA**

**Exclusion Criteria**

Because of the potential risk of osteosarcoma, recommended only for patients who cannot be well-controlled on calcium supplements and active forms of vitamin D alone, has not been studied in patients with hypoparathyroidism caused by calcium-sensing receptor mutations or in patients with acute postsurgical hypoparathyroidism.

**Required Medical Information**

Documented diagnosis of hypocalcemia secondary to hypoparathyroidism.

**Age Restriction**

18 years and older

**Prescriber Restriction**

**Coverage Duration**

Through benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**NERLYNX**

**Exclusion Criteria**

**Required Medical Information**

Documentation of the following diagnosis: 1) the extended adjuvant treatment of adult patients with early stage HER2-overexpressed/amplified breast cancer, to follow adjuvant trastuzumab based therapy OR 2) advanced or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2 based regimens in the metastatic setting and the medication will be used in combination with capecitabine.

**Age Restriction**

**Prescriber Restriction**

Oncologist

**Coverage Duration**

Through the end of benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**NEULASTA**

**Exclusion Criteria**

**Required Medical Information**

For use as primary prophylaxis of febrile neutropenia (FN) in one of the following patients: A) Patient has a 20% or higher risk of FN based on chemotherapy regimen OR B) Patient has a less than 20% risk of developing FN based on chemotherapy regimen AND at least one of the following risk factors are present: 65 years or older, Poor performance status, Poor nutritional status, Previous episodes of febrile neutropenia, Extensive prior treatment including large radiation ports, Cytopenias due to bone marrow involvement by tumor, Administration of combined chemoradiotherapy, Presence of open wounds or active infections, Other serious comorbidities (including renal or liver dysfunction notably elevated bilirubin), or C) Patient is receiving a dose-dense chemotherapy regimen in breast cancer, small cell lung cancer, or non-Hodgkin's lymphoma.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

3 months and is renewable in situations where it continues to provide clinical benefit

**Other Criteria**

Home or LTC administration covered under Medicare Part D. Physician office or healthcare setting administration, redirect for Medicare Part B coverage. Forward to clinical pharmacist to review.

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**NEXAVAR**

**Exclusion Criteria**

Combination use with other tyrosine kinase inhibitors such as sorafenib, sunitinib. Squamous cell lung cancer being treated with carboplatin and paclitaxel.

**Required Medical Information**

Diagnosis of one of the following: A) Advanced renal cell carcinoma, or B) Locally recurrent or metastatic, progressive, differentiated thyroid carcinoma refractory to radioactive iodine treatment, or C) Unresectable hepatocellular carcinoma.

**Age Restriction**

Patient must be at least 18 years old or older.

**Prescriber Restriction**

**Coverage Duration**

Initial: 3 months, Renewal: through end of benefit year w/ stable disease

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**NEXLETOL**

**Exclusion Criteria**

**Required Medical Information**

Clinical documentation (e.g., chart notes, laboratory values) required for initial authorization includes: 1. Documentation of one of the following diagnoses: A) Primary Hyperlipidemia (Including Heterozygous Familial Hypercholesterolemia), OR B) Atherosclerotic cardiovascular disease (ASCVD), AND 2. Documentation of any one of the following: a) Patient has been receiving statin therapy at a maximally tolerated dose and (maximally tolerated dose may include no statin therapy) OR b) Patient has a documented labeled contraindication to all statins OR c) Patient has experienced rhabdomyolysis, AND 3. Patient has tried and failed ezetimibe. Clinical documentation required for reauthorization includes: 1. Physician attestation of medication's efficacy.

**Age Restriction**

18 years or older

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

Other Criteria: Primary Hyperlipidemia (Including Heterozygous Familial Hypercholesterolemia): The patient has a low-density lipoprotein cholesterol (LDL-C level) greater than or equal to 100 mg/dL. C) ASCVD: The patient has a low-density lipoprotein cholesterol (LDL-C) greater than or equal to 70 mg/dL (after treatment with antihyperlipidemic agents. ASCVD diagnosis is confirmed by one of the following: acute coronary syndromes, history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack, peripheral arterial disease presumed to be of atherosclerotic origin.

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**NEXLIZET**

**Exclusion Criteria**

**Required Medical Information**

Clinical documentation (e.g., chart notes, laboratory values) required for initial authorization includes: 1. Documentation of one of the following diagnoses: A) Heterozygous familial hypercholesterolemia, OR B) Atherosclerotic cardiovascular disease (ASCVD) established, AND 2. Documentation of any one of the following: a) Patient has been receiving statin therapy at a maximally tolerated dose (maximally tolerated dose may include no statin therapy), OR b) Patient has a documented labeled contraindication to all statins, OR c) Patient has experienced rhabdomyolysis. Clinical documentation required for reauthorization includes: 1. Physician attestation of medication's efficacy.

**Age Restriction**

18 years and older.

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

Other Criteria: Primary Hyperlipidemia (Including Heterozygous Familial Hypercholesterolemia): The patient has a low-density lipoprotein cholesterol (LDL-C level) greater than or equal to 100 mg/dL. C) ASCVD: The patient has a low-density lipoprotein cholesterol (LDL-C) greater than or equal to 70 mg/dL (after treatment with antihyperlipidemic agents. ASCVD diagnosis is confirmed by one of the following: acute coronary syndromes, history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack, peripheral arterial disease presumed to be of atherosclerotic origin.

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**NINLARO**

**Exclusion Criteria**

**Required Medical Information**

Diagnosis of multiple myeloma AND have received at least one prior therapy AND medication will be used in combination with dexamethasone and lenalidomide.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year.

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## Nitisinone

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### **Drugs**

*nitisinone*

### **Exclusion Criteria**

#### **Required Medical Information**

Required Diagnosis of Hereditary tyrosinemia type 1: Treatment of hereditary tyrosinemia type 1 (HT-1).

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

Through end of benefit year

### **Other Criteria**

### **Indications**

All FDA-approved Indications.

### **Off Label Uses**



**Drugs  
NORTHERA**

**Exclusion Criteria**

**Required Medical Information**

Documentation that patient has a persistent, consistent decrease in systolic blood pressure within 3 minutes of standing AND Northera will be used for patients with neurogenic orthostatic hypotension associated with one of the following diagnoses: 1) Primary autonomic failure due to Parkinson's disease, multiple system atrophy, or pure autonomic failure, OR 2) Dopamine beta hydroxylase deficiency, OR 3) Non-diabetic autonomic neuropathy.

**Age Restriction**

18 years of age or older

**Prescriber Restriction**

**Coverage Duration**

Through benefit year

**Other Criteria**

For renewal, Patient does not have persistent or sustained supine hypertension (SBP more than 180 mmHg or DBP more than 110 mmHg), Patient does not have persistent or sustained standing or sitting hypertension (SBP more than 180 mmHg or DBP more than 110 mmHg), and Patient had improvement in symptoms of NOH. Sustained mean elevated blood pressure that persists for longer than 5 minutes after change in position. Persistent means elevated BP that occurs on more than one occasion on separate physician office visits

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**NOURIANZ**

**Exclusion Criteria**

**Required Medical Information**

Documentation that the medication will be used as an adjunctive treatment to levodopa/carbidopa in adult patients with Parkinson's disease (PD) experiencing "off" episodes.

**Age Restriction**

**Prescriber Restriction**

Neurologist for initial prescription

**Coverage Duration**

Through end of benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**

**NOXAFIL ORAL TABLET,DELAYED RELEASE (DR/EC)**

**Exclusion Criteria**

**Required Medical Information**

1) Prophylaxis against aspergillus or candida infection:? Patient is severely immunocompromised, AND? Prescribed by an Oncologist or Infectious Disease (ID) specialist, AND? Dose does not exceed FDA label maximum.2) Treatment of oropharyngeal candidiasis:? Infection resistant to fluconazole as documented by culture and sensitivity(C&S) result, AND? Dose does not exceed FDA label maximum.3) Treatment of invasive fungal disease:? Dose does not exceed FDA label maximum, AND? One of the following:o Patient has a culture positive for Aspergillus sp, Fusarium sp, ORZygomycetes, ORo Patient has a culture positive Candida sp that is resistant to fluconazoleas documented by culture and sensitivity results, ORo Patient is unresponsive to 1st line recommended therapy.

**Age Restriction**

13 years of age for tablet

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**NUBEQA**

**Exclusion Criteria**

**Required Medical Information**

Documentation of non-metastatic castration resistant prostate cancer (nmCRPC).

**Age Restriction**

**Prescriber Restriction**

Oncologist

**Coverage Duration**

3 months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**NUCALA**

**Exclusion Criteria**

**Required Medical Information**

Documentation that either A) patient has asthma with an eosinophilic phenotype defined as blood eosinophils greater than or equal to 300 cells/ $\mu$ L within previous 12 months or greater than or equal to 150 cells/ $\mu$ L within 6 weeks of dosing AND medication will be used in combination with a corticosteroid inhaler and long acting beta2-agonist AND Patient must have experienced two or more exacerbations in the previous year OR require daily oral corticosteroids OR B) patient has eosinophilic granulomatosis with polyangiitis (EGPA) AND documented trial and failure of or contraindication to treatment with at least one immunosuppressants (azathioprine, cyclophosphamide, or methotrexate).

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

6 months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**NUEDEXTA**

**Exclusion Criteria**

Currently prescribed an MAOI or within 14 days of stopping an MAOI. Diagnosis of AV block (without implanted pacemaker, or patients at high risk of complete AV block), heart failure, QT prolongation or history of torsades de pointes. Concomitant use with drugs that both prolong QT interval and are metabolized by CYP2D6 (e.g., thioridazine or pimozide).

**Required Medical Information**

Initial Authorization Requirement: Clinical diagnosis of Pseudobulbar affect (PBA) as evidenced by ALL of the following: A) PBA Symptom frequency of 4 or more episodes per day, AND B) Baseline score of at least 13 on the Center for Neurologic Studies-Lability Scale (CNS-LS), AND C) Neurologic disease or brain injury (e.g., traumatic brain injury, stroke, dementia, multiple sclerosis, amyotrophic lateral sclerosis (ALS), Parkinson's disease). Reauthorization Requirement: Documentation of clinical benefit with decrease in episodes per day.

**Age Restriction**

18 years or older

**Prescriber Restriction**

Neurologist

**Coverage Duration**

Initial Authorization will be for 3 months. Reauthorization will be for 1 year.

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## NUPLAZID (pimavanserin)

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### Drugs

NUPLAZID ORAL CAPSULE, NUPLAZID ORAL TABLET 10 MG

### Exclusion Criteria

#### Required Medical Information

Documentation that diagnosis of Parkinson's disease was made prior to the onset of psychotic symptoms.

### Age Restriction

### Prescriber Restriction

### Coverage Duration

Through end of benefit year.

### Other Criteria

### Indications

All FDA-approved Indications.

### Off Label Uses

## Nurtec (rimegepant sulfate)

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### **Drugs** **NURTEC ODT**

#### **Exclusion Criteria**

#### **Required Medical Information**

Documentation that the medication will be used for the acute treatment of migraine with or without aura in adults AND the member has tried and failed two alternatives one of which was a triptan, unless contraindicated.

#### **Age Restriction**

#### **Prescriber Restriction**

#### **Coverage Duration**

Through end of benefit year

#### **Other Criteria**

Reauthorization requires documentation of medication efficacy.

#### **Indications**

All FDA-approved Indications.

#### **Off Label Uses**



## Nymalize (nimodipine)

---

### Drugs

**NYMALIZE ORAL SYRINGE 60 MG/10 ML**

### Exclusion Criteria

#### Required Medical Information

Diagnosis of Subarachnoid hemorrhage: For the improvement of neurological outcome by reducing the incidence and severity of ischemic deficits in adult patients with subarachnoid hemorrhage (SAH) from ruptured intracranial berry aneurysms regardless of their postictus neurological condition (ie, Hunt and Hess grades I to V)

### Age Restriction

### Prescriber Restriction

### Coverage Duration

Through end of benefit year

### Other Criteria

### Indications

All FDA-approved Indications.

### Off Label Uses

**Drugs**  
**ODOMZO**

**Exclusion Criteria**

**Required Medical Information**

Documented locally advanced basal cell carcinoma (BCC) that has recurred following surgery or radiation therapy, or the member is a not candidate for surgery or radiation therapy.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year.

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**OFEV**

**Exclusion Criteria**

**Required Medical Information**

The patient has a diagnosis of 1) idiopathic pulmonary fibrosis confirmed by a high resolution CT scan or biopsy AND the patient does not have evidence or suspicion of an alternative interstitial lung disease diagnosis OR 2) Systemic Sclerosis-Associated Interstitial Lung Disease (SSc-ILD) OR 3) Chronic Fibrosing Interstitial Lung Diseases (ILDs), which appear to have FVC cutoffs of 40% and 45% AND liver function tests have been performed prior to start of therapy

**Age Restriction**

18 years and older

**Prescriber Restriction**

Prescribed by or in consultation with a pulmonologist

**Coverage Duration**

Through benefit year

**Other Criteria**

For renewal, patient experienced stabilization from baseline or a less than 10 percent decline in force vital capacity AND the patient has not experienced AST or ALT elevations greater than 5 times the upper limit of normal or greater than 3 times the upper limit of normal with signs or symptoms of severe liver damage.

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**

**OMNITROPE SUBCUTANEOUS CARTRIDGE**

**Exclusion Criteria**

**Required Medical Information**

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**ONUREG**

**Exclusion Criteria**

**Required Medical Information**

Patient has 1) a diagnosis of acute myeloid leukemia, AND 2) achieved first complete remission (CR) or complete remission with incomplete blood count recovery (CRi) following intensive induction chemotherapy AND, is not able to complete intensive curative therapy, AND has tried and failed or has a contraindication to subcutaneous azacitidine.

**Age Restriction**

18 years of age or older

**Prescriber Restriction**

Prescribed by, or in consultation with, an oncologist or hematologist

**Coverage Duration**

Through end of current plan year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**OPSUMIT**

**Exclusion Criteria**

Pregnancy

**Required Medical Information**

Clinically diagnosed with pulmonary arterial hypertension WHO Group 1 that was confirmed by right heart catheterization. Patient has WHO Functional Class II - IV symptoms, AND The patient has had a vasoreactivity test unless the provider indicates that the patient has a contraindication to the test or indicates clinical inappropriateness to the vasoreactivity test, AND Must have tried and failed or has a contraindication to the use of a calcium channel blocker if they have a positive vasoreactivity test, AND If functional class II or III, must have tried and failed or intolerant to sildenafil, or provide documentation as to why contraindicated to initiation of sildenafil.

**Age Restriction**

Patient must be at least 18 years of age

**Prescriber Restriction**

Prescribed by a pulmonologist, a cardiologist, or a physician specializing in pulmonary arterial hypertension.

**Coverage Duration**

3 Months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**

**ORENCIA CLICKJECT, ORENCIA SUBCUTANEOUS SYRINGE 125 MG/ML, 50 MG/0.4 ML, 87.5 MG/0.7 ML**

**Exclusion Criteria**

**Required Medical Information**

Diagnosis of 1 of the following: A) Mod-severe rheumatoid arthritis and trial of 1 or more non-biologic disease modifying anti-rheumatic drugs (DMARD) (e.g., hydroxychloroquine [HCQ], sulfasalazine, methotrexate [MTX], leflunomide, azathioprine, cyclosporine), or B) Mod-severe polyarticular juvenile idiopathic arthritis (JIA) and trial of 1 or more non-biologic DMARDs (e.g., HCQ, sulfasalazine, MTX, leflunomide, azathioprine, cyclosporine), or C) Psoriatic arthritis and trial of MTX. A trial is defined as an inadequate response, intolerance or contraindication to the therapy.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Through end of plan year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**ORENITRAM**

**Exclusion Criteria**

**Required Medical Information**

Patient has a diagnosis of PAH (WHO Group I) WHO/NYHA Class IV patients OR 1.) Patient has a diagnosis of PAH (WHO Group I) WHO/NYHA Class II-III who do not respond adequately to, are unable to tolerate, or are not candidates for one endothelin receptor antagonists (e.g. TRACLEER [bosentan] or LETAIRIS [ambrisentan]) and one phosphodiesterase-5 (PDE-5) inhibitors (e.g. REVATIO [sildenafil], ADCIRCA [tadalafil]).

**Age Restriction**

Patient must be at least 18 years of age.

**Prescriber Restriction**

Prescribed by a pulmonologist or a cardiologist

**Coverage Duration**

3 Months

**Other Criteria**

Medication is eligible for B vs. D determination

**Indications**

All FDA-approved Indications.

**Off Label Uses**



**Drugs**  
**ORGOVYX**

**Exclusion Criteria**

**Required Medical Information**

Patient has a diagnosis of advanced prostate cancer

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

12 months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**ORKAMBI ORAL TABLET**

**Exclusion Criteria**  
Use in combination with Kalydeco

**Required Medical Information**  
The patient is positive for the F508del mutation on both alleles of the CFTR gene.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**  
Through end of benefit year.

**Other Criteria**

**Indications**  
All FDA-approved Indications.

**Off Label Uses**

**Drugs**

OTEZLA, OTEZLA STARTER ORAL TABLETS,DOSE PACK 10 MG (4)-20 MG (4)-30 MG (47)

**Exclusion Criteria**

**Required Medical Information**

Documented negative Tuberculin test prior to therapy AND patient is free of any clinically important active infections.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## OXANDROLONE

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### Drugs

*oxandrolone oral tablet 10 mg, 2.5 mg*

### Exclusion Criteria

Pregnancy Category X

### Required Medical Information

Statement indicating use to promote weight gain after weight loss following extensive surgery, chronic infections, or severe trauma, and in some patients who without definite pathophysiologic reasons fail to gain or to maintain normal weight, and to offset the protein catabolism associated with prolonged administration of corticosteroids. Statement indicating use for orphan drug indication, short stature associated with Turner syndrome, constitutional delay of growth and puberty, moderate or severe acute alcoholic hepatitis, Duchenne and Becker muscular dystrophy. Initial Therapy for AIDS Wasting: Diagnosis of AIDS wasting/cachexia. For treatment of anorexia associated with weight loss in patients with HIV: 1. Patient is receiving AIDS anti-retroviral therapy AND 2. experienced as least a. 7.5% unintentional weight loss over 6 months b. 10% unintentional weight loss over 12 months c. 5% body cell mass (BCM) loss within 6 months d. BMI less than 20 kg/m<sup>2</sup> e. BCM less than 35% male (less than 23% female) and a BMI less than 27 kg/m<sup>2</sup> AND 3. documentation of trial and failure, contraindication, or intolerance to megestrol at doses up to 800mg daily.

### Age Restriction

### Prescriber Restriction

### Coverage Duration

HIV Wasting: 3 months. All other indications: Through the Benefit Year

### Other Criteria

### Indications

All Medically-accepted Indications.

### Off Label Uses

**Drugs**  
**OXBRYTA**

**Exclusion Criteria**

**Required Medical Information**

Documentation that the patient has the diagnosis of sickle cell disease AND has experienced at least one sickle cell-related vaso-occlusive crisis within the past 12 months AND has a baseline hemoglobin range that is greater than or equal to 5.5 g/dL and less than or equal to 10.5 g/dL.?

**Age Restriction**

Patient is 12 years of age or older.

**Prescriber Restriction**

Prescribed by or in consultation with a hematologist, or other specialist with expertise in the diagnosis and management of sickle cell disease.

**Coverage Duration**

6 Months

**Other Criteria**

Continuation of therapy requires documentation of improved clinical benefit to therapy as demonstrated by increase in hemoglobin by 1g/dL from baseline, decrease in the number of sickle cell-related vaso-occlusive crises, decrease in percent reticulocyte count from baseline, decrease in indirect bilirubin count from baseline, or physician attestation.

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## Oxervate (cenegermin)

---

### **Drugs** **OXERVATE**

#### **Exclusion Criteria**

#### **Required Medical Information**

Member has a diagnosis (documented in chart notes) of neurotrophic keratitis in the affected eye(s) AND Member is refractory to at least ONE conventional non-surgical treatment for neurotrophic keratitis (e.g. topical antibiotic eyedrops)

#### **Age Restriction**

Member is 2 years of age or older

#### **Prescriber Restriction**

The medication is prescribed by an ophthalmologist

#### **Coverage Duration**

8 weeks

#### **Other Criteria**

#### **Indications**

All FDA-approved Indications.

#### **Off Label Uses**

**Drugs**  
**PALYNZIQ**

**Exclusion Criteria**

Not to be used in combination with sapropterin dihydrochloride (Kuvan)

**Required Medical Information**

Documented Diagnosis of Phenylketonuria (PKU), AND blood phenylalanine concentration greater than 600 micromol/L, AND physician agrees to assess patient tolerability, blood phenylalanine concentration, AND prescriber and patient must be enrolled with the Palynziq REMS Program.

**Age Restriction**

18 years of age and older

**Prescriber Restriction**

**Coverage Duration**

3 Months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**

**PRALUENT PEN, REPATHA PUSHTRONEX, REPATHA SURECLICK, REPATHA SYRINGE**

**Exclusion Criteria**

**Required Medical Information**

Clinical documentation (e.g., chart notes, laboratory values) required for initial authorization includes: 1. Documentation of one of the following diagnoses: A) Homozygous familial hypercholesterolemia (HoFH)(Repatha only), B) Primary Hyperlipidemia (Including Heterozygous Familial Hypercholesterolemia), OR C) Atherosclerotic cardiovascular disease (ASCVD), AND 2. Documentation of any one of the following: a) Patient has been receiving statin therapy at a maximally tolerated dose and will continue to receive statin at maximally tolerated dose (maximally tolerated dose may include no statin therapy), b) Patient has a documented labeled contraindication to all statins, c) Patient has experienced rhabdomyolysis. Clinical documentation required for reauthorization includes: 1. Physician attestation of medication's efficacy. For statin intolerant patients, we will cover pcsk9s without the member having to use statin therapy.

**Age Restriction**

HeFH, ASCVD: 18 years and older. HoFH: 13 years and older

**Prescriber Restriction**

Prescribed by or in consultation with or recommendation of, a Cardiologist, Endocrinologist, Lipid specialist

**Coverage Duration**

Initial Authorization will be for 6 months. Reauthorization will be for 1 year

**Other Criteria**

Other Criteria: A) HoFH: Patient meets one of the following: a) Patient has genetic confirmation of two mutant alleles at LDLR, APOB, PCSK9 or LDLRAP1 gene locus OR b) Patient has an untreated LDL-C level greater than 500 mg/dL (prior to treatment with antihyperlipidemic agents) OR c) Patient has a treated LDL-C level greater than or equal to 300 mg/dL (after treatment with antihyperlipidemic agents but prior to agents such as Repatha, Kynamro, or Juxtapid) OR d) Patient has clinical manifestations of HoFH (e.g., cutaneous xanthomas, tendon xanthomas, arcus cornea, tuberous xanthomas or xanthelasma B) Primary Hyperlipidemia (Including Heterozygous Familial Hypercholesterolemia): The patient has a low-density lipoprotein cholesterol (LDL-C level) greater than or equal to 100 mg/dL (after treatment with antihyperlipidemic agents but prior to PCSK9 inhibitor therapy. C) ASCVD: The patient has a low-density lipoprotein cholesterol (LDL-C) greater than or equal to 70 mg/dL (after treatment with antihyperlipidemic agents but prior to PCSK9 inhibitor therapy. ASCVD diagnosis is confirmed by one of the following: acute coronary syndromes, history of myocardial infarction, stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack, peripheral arterial disease presumed to be of atherosclerotic origin.

**Indications**

All FDA-approved Indications.

**Off Label Uses**



**Drugs**

**PEGASYS SUBCUTANEOUS SOLUTION, PEGASYS SUBCUTANEOUS SYRINGE**

**Exclusion Criteria**

Decompensated cirrhosis (Child Turcotte Pugh class B or C)

**Required Medical Information**

Diagnosis supporting covered indication. Criteria will be applied consistent with current AASLD-IDSA guidance.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**PEMAZYRE**

**Exclusion Criteria**

**Required Medical Information**

Documentation that the member has been diagnosed with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test.

**Age Restriction**

**Prescriber Restriction**

Oncologist

**Coverage Duration**

3 Months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## Perseris (risperidone)

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### **Drugs** **PERSERIS**

### **Exclusion Criteria**

#### **Required Medical Information**

Documented trial of any of the two following drugs: aripiprazole, clozapine, olanzapine, risperidone, quetiapine, ziprasidone

### **Age Restriction**

### **Prescriber Restriction**

#### **Coverage Duration**

Through the benefit year

### **Other Criteria**

#### **Indications**

All FDA-approved Indications.

### **Off Label Uses**

## Piqray (alpelisib)

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### Drugs

PIQRAY ORAL TABLET 200 MG/DAY (200 MG X 1), 250 MG/DAY (200 MG X1-50 MG X1), 300 MG/DAY (150 MG X 2)

### Exclusion Criteria

#### Required Medical Information

Documentation that the patient is a postmenopausal female or a male AND has advanced or metastatic breast cancer AND has HR-positive disease AND has HER2-negative disease AND has PIK3CA-mutated breast cancer as detected by a FDA approved test AND has progressed on or after at least one prior endocrine-based regimen AND the medication will be used in combination with fulvestrant.

### Age Restriction

### Prescriber Restriction

Oncologist

### Coverage Duration

3 Months

### Other Criteria

### Indications

All FDA-approved Indications.

### Off Label Uses

## POMALYST

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### **Drugs** **POMALYST**

#### **Exclusion Criteria**

##### **Required Medical Information**

Patient has a diagnosis of 1) multiple myeloma and the patient has received two prior therapies, including Revlimid and Velcade unless the patient has a contraindication or intolerance to Revlimid or Velcade and the patient has demonstrated disease progression on or within 60 days of completion of last therapy OR 2) Kaposi sarcoma (KS).

#### **Age Restriction**

#### **Prescriber Restriction**

#### **Coverage Duration**

3 Months

#### **Other Criteria**

Prescriber, pharmacist, and patient must be enrolled in the Pomalyst REMS program.

#### **Indications**

All FDA-approved Indications.

#### **Off Label Uses**

## POSACONAZOLE

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### Drugs

*posaconazole oral tablet, delayed release (DRIEC)*

### Exclusion Criteria

#### Required Medical Information

1) Prophylaxis against aspergillus or candida infection: Patient is severely immunocompromised, AND? Prescribed by an Oncologist or Infectious Disease (ID) specialist, AND? Dose does not exceed FDA label maximum. 2) Treatment of oropharyngeal candidiasis: Infection resistant to fluconazole as documented by culture and sensitivity (C&S) result, AND? Dose does not exceed FDA label maximum. 3) Treatment of invasive fungal disease: Dose does not exceed FDA label maximum, AND? One of the following: o Patient has a culture positive for Aspergillus sp, Fusarium sp, OR Zygomycetes, OR o Patient has a culture positive Candida sp that is resistant to fluconazole as documented by culture and sensitivity results, OR o Patient is unresponsive to 1st line recommended therapy.

#### Age Restriction

13 years and older for tablet

#### Prescriber Restriction

#### Coverage Duration

Through end of benefit year

#### Other Criteria

#### Indications

All FDA-approved Indications.

#### Off Label Uses

**Drugs**

**PROMACTA ORAL POWDER IN PACKET 12.5 MG, PROMACTA ORAL TABLET**

**Exclusion Criteria**

**Required Medical Information**

Diagnosis of one of the following: A) Relapsed/refractory chronic immune (idiopathic) thrombocytopenic purpura (ITP) for greater than 6 months AND Baseline platelet count is less than 50,000/mcL AND Degree of thrombocytopenia and clinical condition increase the risk of bleeding AND Patient had an insufficient response, intolerance, contraindication to corticosteroids or immune globulin or inadequate response or contraindication to splenectomy, or B) Chronic hepatitis C and patient has thrombocytopenia defined as platelets less than 90,000/mcL for initiation (pre-treatment) of interferon therapy, or C) Severe aplastic anemia.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

3 Months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## PULMOZYME

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### **Drugs** **PULMOZYME**

#### **Exclusion Criteria**

#### **Required Medical Information**

Diagnosis of cystic fibrosis.

#### **Age Restriction**

#### **Prescriber Restriction**

#### **Coverage Duration**

Through end of benefit year

#### **Other Criteria**

Pulmozyme should be used in conjunction with standard therapies for CF. For renewal, Patient is benefiting from treatment (i.e. improvement in lung function [FEV1], decreased number of pulmonary exacerbations).

#### **Indications**

All FDA-approved Indications.

#### **Off Label Uses**



## PURIXAN

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### **Drugs PURIXAN**

#### **Exclusion Criteria**

#### **Required Medical Information**

Documentation of acute lymphoblastic leukemia (ALL) AND medication will be used as a component of a combination maintenance therapy regimen.

#### **Age Restriction**

#### **Prescriber Restriction**

#### **Coverage Duration**

Through benefit year

#### **Other Criteria**

#### **Indications**

All FDA-approved Indications.

#### **Off Label Uses**

**Drugs**  
**QINLOCK**

**Exclusion Criteria**

**Required Medical Information**

Required diagnosis of Gastrointestinal stromal tumor, advanced AND must have previously received treatment with more than 3 kinase inhibitors, including imatinib.

**Age Restriction**

For adults only

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## QUININE

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### **Drugs**

*quinine sulfate*

### **Exclusion Criteria**

Treatment of nocturnal leg cramps

### **Required Medical Information**

Documented diagnosis of *Plasmodium falciparum* malaria

### **Age Restriction**

### **Prescriber Restriction**

### **Coverage Duration**

For malaria the authorization is for 7 days. For babesiosis the authorization is 10 days.

### **Other Criteria**

### **Indications**

All Medically-accepted Indications.

### **Off Label Uses**

**Drugs**  
**RAVICTI**

**Exclusion Criteria**

Acute hyperammonemia. N-acetylglutamate synthase (NAGS) deficiency

**Required Medical Information**

Diagnosis of urea cycle disorder involving deficiencies of carbamoyl phosphate synthetase (CPS), ornithine transcarbamoylase (OTC), or argininosuccinic acid synthetase (AAS) confirmed via enzymatic, biochemical, or genetic testing AND patient has tried and had an inadequate response, is intolerant, or has a contraindication to Buphenyl for at least 3 months.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Through benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**

**RETEVMO ORAL CAPSULE 40 MG, 80 MG**

**Exclusion Criteria**

**Required Medical Information**

Diagnosis of one of the following, and treatment in the following populations: A) Non-small cell lung cancer, metastatic, RET fusion-positive: Treatment of metastatic RET fusion-positive non-small cell lung cancer (NSCLC) in adults. B) Thyroid cancer, medullary, RET-mutant: Treatment of advanced or metastatic RET-mutant medullary thyroid cancer (MTC) in adults and pediatric patients 12 years of age or older who require systemic therapy. OR C) Thyroid cancer, RET fusion-positive: Treatment of advanced or metastatic RET fusion-positive thyroid cancer in adults and pediatric patients 12 years of age or older who require systemic therapy and who are refractory to radioactive iodine (if radioactive iodine is appropriate).

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**REVLIMID**

**Exclusion Criteria**  
Pregnancy (category X)

**Required Medical Information**  
Diagnosis of one of the following: A) Multiple myeloma used in combination with dexamethasone, or B) Diagnosis of transfusion-dependent anemia due to low- or intermediate-1-risk myelodysplastic syndromes associated with a deletion 5q cytogenetic abnormality with or without additional cytogenetic abnormalities, or C) Mantle cell lymphoma and patient's disease has relapsed or progressed after trying at least two prior therapies (Velcade and one of the following: bendamustine, cladribine, fludarabine, rituximab), or D) previously treated follicular lymphoma and the medication will be used in combination with rituximab, or E) previously treated marginal zone lymphoma and the medication will be used in combination with rituximab AND patient is enrolled in the Revlimid REMS Program.

**Age Restriction**  
18 years and older

**Prescriber Restriction**  
Hematologist/oncologist. Registered in Revlimid REMS.

**Coverage Duration**  
3 Months

**Other Criteria**

**Indications**  
All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**REYVOW**

**Exclusion Criteria**

**Required Medical Information**

Documentation that the medication will be used for the acute treatment of migraine with or without aura in adults AND the member has tried and failed two alternatives one of which was a triptan, unless contraindicated.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

Reauthorization requires documentation of medication efficacy.

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## Rinvoq (upadacitinib)

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### Drugs RINVOQ

#### Exclusion Criteria

#### Required Medical Information

Diagnosis of 1 of the following: A) Mod-severe rheumatoid arthritis and trial of 1 or more non-biologic disease modifying anti-rheumatic drugs (DMARD) (e.g., hydroxychloroquine [HCQ], sulfasalazine, methotrexate [MTX], leflunomide, azathioprine, cyclosporine)

#### Age Restriction

#### Prescriber Restriction

#### Coverage Duration

Through end of plan year

#### Other Criteria

#### Indications

All FDA-approved Indications.

#### Off Label Uses



## RISPERDAL CONSTA

---

### Drugs

RISPERDAL CONSTA

### Exclusion Criteria

#### Required Medical Information

Documented trial of any of the two following drugs: aripiprazole, clozapine, olanzapine, risperidone, quetiapine, ziprasidone

### Age Restriction

### Prescriber Restriction

#### Coverage Duration

Through end of benefit year.

### Other Criteria

#### Indications

All FDA-approved Indications.

### Off Label Uses

**Drugs**  
**ROZLYTREK**

**Exclusion Criteria**

**Required Medical Information**

Documentation of: A)metastatic non-small cell lung cancer (NSCLC) whose tumors are ROS1-positive OR B) solid tumors that have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion without a known acquired resistance mutation AND are metastatic or where surgical resection is likely to result in severe morbidity AND have either progressed following treatment or have no satisfactory alternative therapy.

**Age Restriction**

12 years of age or older

**Prescriber Restriction**

Oncology

**Coverage Duration**

3 months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**RUBRACA**

**Exclusion Criteria**

**Required Medical Information**

Documented diagnosis of: 1) recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer that had a complete or partial response to platinum-based chemotherapy OR 2) Deleterious BRCA mutation-associated epithelial ovarian, fallopian tube, or primary peritoneal cancer that has been treated with two or more chemotherapies. OR 3) Metastatic Castration-Resistant Prostate Cancer (mCRPC) with BRCA Mutations AND patient has been treated with androgen receptor-directed therapy and a taxane-based chemotherapy.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**RYDAPT**

**Exclusion Criteria**

**Required Medical Information**

Documentation of: 1) Newly diagnosed acute myeloid leukemia (AML) who are FLT3 mutation-positive, as detected by a FDA approved test and will be used in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation OR 2) Aggressive systemic mastocytosis (ASM), systemic mastocytosis with associated hematological neoplasm (SM-AHN), or mast cell leukemia (MCL)

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## SABRIL

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### **Drugs**

*vigabatrin*

### **Exclusion Criteria**

#### **Required Medical Information**

Diagnosis of one of the following: A) Refractory complex partial seizures (CPS) AND has previously tried and failed two medications for the diagnosis of refractory complex partial seizures (i.e. carbamazepine, ethotoin, felbamate, fosphenytoin, gabapentin, lacosamide, lamotrigine, levetiracetam, oxcarbazepine, phenytoin, pregabalin, primidone, tiagabine, topiramate, valproic acid, divalproex sodium, zonisamide), or B) Infantile spasms (IS)

### **Age Restriction**

#### **Prescriber Restriction**

Neurologist registered with the Vigabatrin REMS program

#### **Coverage Duration**

Through end of benefit year

### **Other Criteria**

#### **Indications**

All FDA-approved Indications.

### **Off Label Uses**

**Drugs**  
**SAMSCA**

**Exclusion Criteria**

Samsca not approved as an intervention to raise serum sodium urgently to prevent or to treat serious neurological symptoms. Samsca should not be initiated or re-initiated outside of a hospital setting.

**Required Medical Information**

Serum sodium levels. Initial therapy for hyponatremia (hypervolemic and euvolemic): 1. Diagnosis of significant hyponatremia (euvolemic or hypervolemic), AND 2. Treatment has been initiated or re-initiated in a hospital setting prior to discharge. Reauthorization for hypervolemic and euvolemic hyponatremia: 1. Documentation of clinical benefit, AND 2. Treatment has been initiated or re-initiated in a hospital setting prior to discharge.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

1 month

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## SAPHRIS (asenapine)

---

### **Drugs**

*asenapine maleate*, **SAPHRIS**

### **Exclusion Criteria**

#### **Required Medical Information**

Documented trial of any of the two following drugs: aripiprazole, clozapine, olanzapine, risperidone, quetiapine, ziprasidone

### **Age Restriction**

### **Prescriber Restriction**

#### **Coverage Duration**

Through end of benefit year.

### **Other Criteria**

#### **Indications**

All FDA-approved Indications.

### **Off Label Uses**

## Sapropterin Dihydrochloride

---

### Drugs

*sapropterin oral tablet, soluble*

### Exclusion Criteria

#### Required Medical Information

Documented diagnosis of hyperphenylalaninemia (HPA) due to tetrahydrobiopterin- (BH<sub>4</sub>-) responsive Phenylketonuria (PKU).

### Age Restriction

### Prescriber Restriction

### Coverage Duration

Initial: 3 months. Renewal: through end of benefit year

### Other Criteria

For renewal, patient has been determined to be a responder to therapy (i.e. phenylalanine levels have decreased by at least 30% from baseline).

### Indications

All FDA-approved Indications.

### Off Label Uses



## Secuado (Asenapine)

---

### **Drugs** **SECUADO**

#### **Exclusion Criteria**

#### **Required Medical Information**

Diagnosis of Schizophrenia AND documented treatment failure or intolerable side effects from treatment with two formulary antipsychotic medications such as risperidone, ziprasidone, aripiprazole, olanzapine, and quetiapine.

#### **Age Restriction**

#### **Prescriber Restriction**

#### **Coverage Duration**

Through end of plan year

#### **Other Criteria**

#### **Indications**

All FDA-approved Indications.

#### **Off Label Uses**

**Drugs**

**SEROSTIM SUBCUTANEOUS RECON SOLN 4 MG, 5 MG, 6 MG**

**Exclusion Criteria**

Acute critical illness due to complications following open heart or abdominal surgery, multiple accidental trauma or acute respiratory failure. Active malignancy. Active proliferative or severe non-proliferative diabetic retinopathy.

**Required Medical Information**

Diagnosis of AIDS-wasting syndrome or cachexia (defined as unintentional weight loss of at least 10% of baseline weight) AND Treatment failure with or intolerance to dronabinol or megestrol AND Patient is currently receiving treatment with antiretrovirals.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

3 months initial, renewable every 6 months

**Other Criteria**

For renewal, patient has experienced an increase in body weight and/or improvement in lead body mass AND wasting is still evident.

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## **SIGNIFOR**

---

### **Drugs SIGNIFOR**

#### **Exclusion Criteria**

#### **Required Medical Information**

Documentation of Cushing's Disease diagnosis AND pituitary surgery is not an option or has not been curative

#### **Age Restriction**

#### **Prescriber Restriction**

#### **Coverage Duration**

Through benefit year

#### **Other Criteria**

For renewal, patient had a clinically meaningful reduction in 24-hour urinary free cortisol levels and/or improvement in signs or symptoms of the disease

#### **Indications**

All FDA-approved Indications.

#### **Off Label Uses**

## SILDENAFIL 20 MG (REVATIO)

---

### **Drugs**

*sildenafil (pulm.hypertension) oral tablet*

### **Exclusion Criteria**

Should not be used in combination with organic nitrates. This product is only indicated for Pulmonary Hypertension and is not to be used for Erectile Dysfunction.

### **Required Medical Information**

Statement of FDA approved diagnosis of pulmonary arterial hypertension

### **Age Restriction**

18 years and older

### **Prescriber Restriction**

Cardiologist or Pulmonologist

### **Coverage Duration**

Through end of benefit year

### **Other Criteria**

### **Indications**

All FDA-approved Indications.

### **Off Label Uses**

**Drugs**  
**SIRTURO****Exclusion Criteria**

Bedaquiline should not be used for latent, extrapulmonary (eg, CNS), or drug-sensitive TB, or non-TB mycobacteria.

**Required Medical Information**

Diagnosis of pulmonary multidrug-resistant tuberculosis (MDR-TB). Bedaquiline should only be used in combination with at least 3 other drugs to which the patient's MDR-TB isolate has been shown to be susceptible in vitro. If in vitro testing results are unavailable, treatment may be initiated with bedaquiline in combination with at least 4 other drugs to which the patient's MDR-TB isolate is likely to be susceptible. Isolates from patients who fail to convert or relapse following treatment should be tested for bedaquiline minimum inhibitory concentrations.

**Age Restriction**

patients 5 years of age and older and weighing at least 15 kg.

**Prescriber Restriction****Coverage Duration**

24 weeks

**Other Criteria**

Use for more than 24 weeks should be evaluated on a case-by-case basis. Bedaquiline should be administered by directly observed therapy (DOT). Throughout treatment with, and following the last dose, patients should continue to take their companion drugs as directed.

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**

**SKYRIZI SUBCUTANEOUS SYRINGE KIT**

**Exclusion Criteria**

**Required Medical Information**

Diagnosis of Mod-severe chronic plaque psoriasis (affecting more than 5% of body surface area or crucial body areas such as the hands, feet, face, or genitals) and trial of at least one oral systemic treatment (e.g., MTX, cyclosporine, acitretin, sulfasalazine)

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Through end of plan year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**

*sofosbuvir-velpatasvir*

**Exclusion Criteria**

**Required Medical Information**

Provider must submit medical records documenting the following: 1) medical diagnosis of Chronic Hepatitis C with labs documenting genotype and subtype, AND 2) medical records documenting viral load taken within 6 months of beginning therapy

**Age Restriction**

6 years of age and older

**Prescriber Restriction**

Prescribed by, or in consultation with, a gastroenterologist, hepatologist, or infectious disease physician.

**Coverage Duration**

12 weeks or as defined by current AASLD/IDSA guidance

**Other Criteria**

Criteria and coverage durations will be applied consistent with current AASLD/IDSA guidance.

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## SOMATULINE

---

### Drugs

#### SOMATULINE DEPOT

#### Exclusion Criteria

#### Required Medical Information

Diagnosis of A) acromegaly AND Inadequate response to surgery and/or radiation therapy or patient cannot be treated with surgery and/or radiotherapy, or B) unresectable, well or moderately differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors (GEP-NETs), or C) carcinoid syndrome.

#### Age Restriction

18 years of age and older

#### Prescriber Restriction

#### Coverage Duration

3 months initial. Continuation 6 months if no progression

#### Other Criteria

For renewal, patient's IGF-1 levels has normalized or improved.

#### Indications

All FDA-approved Indications.

#### Off Label Uses



**Drugs**  
**SPRYCEL**

**Exclusion Criteria**

**Required Medical Information**

Diagnosis of one of the following: A) Newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase, or B) Chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML AND failure, resistance, or intolerance to imatinib, or C) Philadelphia chromosome-positive (Ph+) acute lymphoblastic leukemia (ALL) with resistance or intolerance to imatinib, or D) Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase for pediatric patients.

**Age Restriction**

**Prescriber Restriction**

Prescriber must be an oncologist.

**Coverage Duration**

Through end of benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## Stelara (Ustekinumab)

---

### Drugs

#### STELARA SUBCUTANEOUS

#### Exclusion Criteria

#### Required Medical Information

Diagnosis of 1 of the following: A) Mod-severe Crohn disease and trial of Humira and a corticosteroid OR B) Psoriatic arthritis and trial and failure of 2 or more of the following: Humira, Enbrel, Xeljanz, Cosentyx, and Otezla, or C) Mod-severe chronic plaque psoriasis (affecting more than 5% of body surface area or crucial body areas such as the hands, feet, face, or genitals) and trial of 2 or more of the following: Humira, Enbrel, Cosentyx, and Otezla, or D) moderately to severely active ulcerative colitis and trial of Humira and corticosteroids.

#### Age Restriction

6 years and older for Psoriasis and 18 years of age and older for all other indications

#### Prescriber Restriction

Gastroenterologist for Crohn disease diagnosis

#### Coverage Duration

6 months

#### Other Criteria

Negative Tuberculin test prior to therapy AND patient is free of any clinically important active infections

#### Indications

All FDA-approved Indications.

#### Off Label Uses

**Drugs**  
**STIVARGA****Exclusion Criteria****Required Medical Information**

Diagnosis of one of the following: A) Metastatic colorectal cancer AND patient has previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based therapy, an anti-vascular endothelial growth factor (VEGF) therapy, and, if KRAS wild type, an anti-epidermal growth factor receptor (EGFR) therapy, or B) Gastrointestinal stromal tumors that is locally advanced, unresectable or metastatic and patient has tried and had an inadequate response, contraindication or intolerance to Gleevec or Sutent, or C) Hepatocellular carcinoma (HCC) and patient has been previously treated with sorafenib.

**Age Restriction**

18 years and older

**Prescriber Restriction**

Oncologist

**Coverage Duration**

3 Months

**Other Criteria**

Hepatic function will be monitored prior to and during treatment and, if patient has elevated liver function tests of hepatocellular necrosis, therapy will be interrupted and then reduced or discontinued.

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## SUCRAID

---

### Drugs SUCRAID

#### Exclusion Criteria

#### Required Medical Information

Diagnosis of congenital sucrose-isomaltase deficiency confirmed by: 1) Duodenal biopsy showing low sucrose activity and normal amounts of other disaccharides OR 2) Stool pH less than 6, increase in breath hydrogen of greater than 10ppm when challenged with sucrose after fasting, and negative lactose breath test.

#### Age Restriction

#### Prescriber Restriction

Prescribed by a gastroenterologist, endocrinologist, or genetic specialist

#### Coverage Duration

3 Months

#### Other Criteria

#### Indications

All FDA-approved Indications.

#### Off Label Uses

## Sunosi (Solriamfetol)

---

### Drugs SUNOSI

#### Exclusion Criteria

#### Required Medical Information

Clinical documentation of narcolepsy or obstructive sleep apnea AND failed at least TWO alternatives (e.g. methylphenidate, dextroamphetamine, modafinil and armodafinil).

#### Age Restriction

#### Prescriber Restriction

#### Coverage Duration

Through the plan year

#### Other Criteria

#### Indications

All FDA-approved Indications.

#### Off Label Uses

**Drugs**  
**SUTENT**

**Exclusion Criteria**

Combination use with other kinase inhibitors (for example, sorafenib, etc).

**Required Medical Information**

Diagnosis of one of the following: A) Advanced/metastatic renal cell carcinoma, or B) Gastrointestinal stromal tumors after disease progression on or intolerance to Gleevec, or C) Progressive, well-differentiated pancreatic neuroendocrine tumors in a patient with unresectable locally advanced or metastatic disease, or D) recurrent Renal Cell Carcinoma (RCC) following nephrectomy.

**Age Restriction**

Patient must be at least 18 years of age.

**Prescriber Restriction**

Must be prescribed by oncologist

**Coverage Duration**

3 months initial, then renewable in 6 month increments

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## Sympazan (Clobazam)

---

### Drugs SYMPAZAN

#### Exclusion Criteria

#### Required Medical Information

Diagnosis of Lennox-Gastaut syndrome AND is being used as adjunctive therapy AND rationale for requiring oral film formulation.

#### Age Restriction

2 years and older

#### Prescriber Restriction

Prescribed by or in consultation with a neurologist.

#### Coverage Duration

Initial: 3 months, Renewal: through end of benefit year w/ stable disease

#### Other Criteria

#### Indications

All FDA-approved Indications.

#### Off Label Uses

**Drugs**  
**SYNRIBO**

**Exclusion Criteria**

**Required Medical Information**

Diagnosis of chronic myelogenous leukemia (CML) AND patient has tried and failed or has a contraindication or intolerance to two prior tyrosine kinase inhibitor therapies [eg, Gleevec (imatinib), Sprycel (dasatinib), Tasigna (nilotinib), Bosulif (bosutinib)].

**Age Restriction**

18 years of age or older

**Prescriber Restriction**

Prescribed by a hematologist and/or oncologist

**Coverage Duration**

3 Months

**Other Criteria**

Medication is eligible for B vs. D determination

**Indications**

All FDA-approved Indications.

**Off Label Uses**



**Drugs**  
**TABRECTA**

**Exclusion Criteria**

**Required Medical Information**

Diagnosis of Non-small cell lung cancer, metastatic (with mesenchymal-epithelial transition [MET] exon 14 skipping mutation)

**Age Restriction**

**Prescriber Restriction**

Oncology

**Coverage Duration**

Through end of benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## TAFINLAR

---

### Drugs

TAFINLAR ORAL CAPSULE 50 MG, 75 MG

### Exclusion Criteria

#### Required Medical Information

Diagnosis of unresectable or metastatic melanoma along with BRAF V600E or BRAF V600K mutation status as detected by a US Food and Drug Administration-approved test.

#### Age Restriction

18 years or older

#### Prescriber Restriction

Oncologist

#### Coverage Duration

3 Months

### Other Criteria

#### Indications

All FDA-approved Indications.

### Off Label Uses

**Drugs**  
**TAGRISSO**

**Exclusion Criteria**

**Required Medical Information**

Documented diagnosis of: 1) metastatic non-small cell lung cancer (NSCLC) with tumors that have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test OR 2) metastatic EGFR T790M mutation-positive NSCLC, as detected by an FDA-approved test, with disease progression on or after EGFR tyrosine kinase inhibitor (TKI) therapy.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year.

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## Talzenna (Talzoparib)

---

### Drugs

TALZENNA ORAL CAPSULE 0.25 MG, 1 MG

### Exclusion Criteria

#### Required Medical Information

Documentation of deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA)-mutated (gBRCAm) human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer.

### Age Restriction

#### Prescriber Restriction

Oncology

#### Coverage Duration

3 months

### Other Criteria

#### Indications

All FDA-approved Indications.

### Off Label Uses

**Drugs**  
*erlotinib*

**Exclusion Criteria**

**Required Medical Information**

Diagnosis of one of the following: A) Locally advanced, unresectable, or metastatic pancreatic cancer and erlotinib will be used in combination with gemcitabine, or B) First-line treatment of metastatic non-small cell lung cancer in which tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 (L858R) substitution mutations as detected by an Food and Drug Administration (FDA)-approved test, or C) Maintenance treatment of locally advanced or metastatic non-small cell lung cancer when disease has not progressed after 4 cycles of platinum-based first-line chemotherapy, or D) Treatment of locally advanced or metastatic non-small cell lung cancer after failure of at least 1 prior chemotherapy regimen.

**Age Restriction**

18 years or older

**Prescriber Restriction**

Prescriber must be an oncologist.

**Coverage Duration**

Through end of benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## Targretin

---

**Drugs**  
**TARGRETIN TOPICAL**

**Exclusion Criteria**

**Required Medical Information**

Diagnosis of Cutaneous T-cell lymphoma: refractory or persistent, early stage.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**TASIGNA**

**Exclusion Criteria**

Long QT syndrome. Uncorrected hypokalemia. Uncorrected hypomagnesemia. Concomitant use with a drug known to prolong the QT interval or strong cytochrome P450 3A4 inhibitors.

**Required Medical Information**

Diagnosis of one of the following: A) Newly diagnosed adult patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase, or B) Ph+ chronic or accelerated phase chronic myeloid leukemia (CML) in adult patients resistant to or intolerant to prior therapy that included imatinib, or C) Ph+ chronic phase chronic myeloid leukemia (CML) in pediatric patients resistant to or intolerant to prior tyrosine-kinase inhibitor (TKI) therapy.

**Age Restriction**

**Prescriber Restriction**

Must be prescribed by Oncologist

**Coverage Duration**

Initial: 3 months, Renewal: 6 months with documentation of continued benefit

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**TAVALISSE**

**Exclusion Criteria**

**Required Medical Information**

Documented Platelet count less than  $30 \times 10^9/L$  and member had an insufficient response to previous treatment (corticosteroids, immunoglobulins, splenectomy, and/or a thrombopoietin receptor agonists)

**Age Restriction**

18 years or older

**Prescriber Restriction**

Hematologist

**Coverage Duration**

Initial Authorization will be for 3 months. Reauthorization will be for 1 year.

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**



**Drugs**  
**TAZVERIK**

**Exclusion Criteria**

**Required Medical Information**

Documentation of 1) metastatic or locally advanced epithelioid sarcoma that is not eligible for complete resection, OR  
2)relapsed or refractory follicular lymphoma whose tumors are positive for an EZH2 mutation AND have received at least  
2 prior systemic therapies OR have no satisfactory alternative treatment options.

**Age Restriction**

**Prescriber Restriction**

Oncology

**Coverage Duration**

3 months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## TECFIDERA

---

### Drugs

TECFIDERA ORAL CAPSULE,DELAYED RELEASE(DR/EC) 120 MG, 120 MG (14)- 240 MG (46), 240 MG

### Exclusion Criteria

Treatment of primary progressive MS is not covered. Combination therapy with a beta interferon product, Gilenya, Aubagio, Tecfidera, Tysabri or Copaxone is not covered.

### Required Medical Information

Diagnosis of relapsing forms of multiple sclerosis (relapsing-remitting MS or progressive-relapsing MS, or secondary-progressive MS) OR patient has experienced a first clinical episode and has MRI features consistent with multiple sclerosis.

### Age Restriction

### Prescriber Restriction

### Coverage Duration

Through end of benefit year

### Other Criteria

### Indications

All FDA-approved Indications.

### Off Label Uses

**Drugs**  
**TEGSEDI**

**Exclusion Criteria**

**Required Medical Information**

Documentation of polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year.

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## Teriparatide

---

### Drugs

*teriparatide*

### Exclusion Criteria

Because of an increased incidence of osteosarcoma, teriparatide should not be prescribed for patients who are at increased baseline risk for osteosarcoma (including those with Paget's disease of bone or unexplained elevations of alkaline phosphatase, open epiphyses, or prior radiation therapy involving the skeleton).

### Required Medical Information

Diagnosis of one of the following: A) Osteoporosis in a postmenopausal female, or B) Primary or hypogonadal osteoporosis in a male, or C) Osteoporosis associated with sustained systemic glucocorticoid therapy AND one or more of the following: 1) History of osteoporotic fracture, or 2) Documented trial and failure of bisphosphonate and Prolia, or 3) Documented contraindication or intolerance to bisphosphonate therapy and Prolia. Patient has not received more than 2 years of therapy with teriparatide.

### Age Restriction

### Prescriber Restriction

### Coverage Duration

Initial: 1 year. Renewal: 1 year not to exceed 2 years of total therapy.

### Other Criteria

Treatment failure is defined as documented continued bone loss after at least three months despite treatment with a bisphosphonate or Prolia. Note: Since the effects of long-term treatment with teriparatide are not known at this time, therapy for more than 2 years duration is considered experimental and investigational.

### Indications

All FDA-approved Indications.

### Off Label Uses

**Drugs**  
**THALOMID**

**Exclusion Criteria**  
Pregnancy (category X)

**Required Medical Information**  
Diagnosis of one of the following: A) Multiple myeloma that is newly diagnosed and is receiving concurrent dexamethasone, or B) Acute treatment of cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL) AND the medication will not be used as monotherapy if the member has moderate to severe neuritis, or C) Maintenance therapy for prevention and suppression of cutaneous manifestations of ENL recurrence.

**Age Restriction**  
12 years of age and older

**Prescriber Restriction**  
Candidates must follow Thalomid REMS program requirements. Provider and pharmacy must be registered with this program.

**Coverage Duration**  
3 months

**Other Criteria**

**Indications**  
All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**TIBSOVO**

**Exclusion Criteria**

**Required Medical Information**

Documentation of A) relapsed or refractory acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test OR B) newly-diagnosed acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation and the patient is greater than or equal to 75 years old or has comorbidities that preclude use of intensive induction chemotherapy.

**Age Restriction**

**Prescriber Restriction**

Oncology

**Coverage Duration**

3 months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## TOBI PODHALER (tobramycin inhalation capsule)

---

### Drugs

TOBI PODHALER INHALATION CAPSULE, W/INHALATION DEVICE

### Exclusion Criteria

#### Required Medical Information

Documented diagnosis of cystic fibrosis with *Pseudomonas aeruginosa*.

#### Age Restriction

6 years and older

#### Prescriber Restriction

#### Coverage Duration

Through end of benefit year.

#### Other Criteria

Patient must have contraindication/intolerance to or failure of tobramycin nebulizer solution (generic)

#### Indications

All FDA-approved Indications.

#### Off Label Uses

## Tolvaptan

---

### **Drugs**

*tolvaptan*

### **Exclusion Criteria**

#### **Required Medical Information**

Medication requested is being used for the treatment of clinically significant hypervolemic and euvolemic hyponatremia

#### **Age Restriction**

18 years old or older

#### **Prescriber Restriction**

#### **Coverage Duration**

Through end of benefit year

#### **Other Criteria**

#### **Indications**

All FDA-approved Indications.

#### **Off Label Uses**



## Topical Diclofenac

---

### Drugs

**PENNSAID TOPICAL SOLUTION IN METERED-DOSE PUMP**

### Exclusion Criteria

#### Required Medical Information

Documented trial, contraindication, or intolerance to diclofenac 1% topical gel.

### Age Restriction

### Prescriber Restriction

### Coverage Duration

Through end of benefit year

### Other Criteria

### Indications

All FDA-approved Indications.

### Off Label Uses

## Topical Retinoid

---

### Drugs

*tazarotene*, TAZORAC TOPICAL CREAM 0.05 %, TAZORAC TOPICAL GEL, *tretinoin*

### Exclusion Criteria

Should not be used for photoaging/wrinkles

### Required Medical Information

Statement of FDA approved diagnosis

### Age Restriction

### Prescriber Restriction

### Coverage Duration

Through end of benefit year

### Other Criteria

### Indications

All FDA-approved Indications.

### Off Label Uses

**Drugs**

*bosentan*, **TRACLEER ORAL TABLET FOR SUSPENSION**

**Exclusion Criteria**

Receiving concomitant cyclosporine A or glyburide therapy. Aminotransferase elevations are accompanied by signs or symptoms of liver dysfunction or injury or increases in bilirubin at least 2 times the upper limit of normal.

**Required Medical Information**

Diagnosis of pulmonary arterial hypertension (PAH) WHO Group I AND New York Heart Association (NYHA) Functional Class II-IV, AND The patient has had a vasoreactivity test unless the provider indicates that the patient has a contraindication to the test or indicates clinical inappropriateness to the vasoreactivity test, AND Must have tried and failed or has a contraindication to the use of a calcium channel blocker if they have a positive vasoreactivity test, AND If the patient is an adult with functional class II or III, must have tried and failed or intolerant to sildenafil, or provide documentation as to why contraindicated to initiation of sildenafil. For female patients, pregnancy must be excluded prior to the start of therapy and documentation that pregnancy will be prevented thereafter with reliable contraception.

**Age Restriction**

Greater or equal to 3 years of age

**Prescriber Restriction**

Available only to those enrolled in the Bosentan REMS program. Prescription is written by or in consultation with a pulmonologist, a cardiologist.

**Coverage Duration**

3 Months

**Other Criteria**

Liver aminotransferases will be measured prior to initiation of treatment and then monthly.

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## Trientine

---

**Drugs**  
*trientine*

**Exclusion Criteria**

**Required Medical Information**

Documented diagnosis of Wilson's disease and the patient is intolerant of penicillamine.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

3 Months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**TRIKAFTA**

**Exclusion Criteria**

Use in combination with other CFTR modulator (Orkambi, Kalydeco, or Symdeko)

**Required Medical Information**

Documentation of Cystic Fibrosis AND confirmation of presence of at least one F508del mutation in CFTR gene through genetic testing.

**Age Restriction**

12 years of age or older

**Prescriber Restriction**

Prescribed by pulmonologist or a physician who specializes in the treatment of Cystic fibrosis

**Coverage Duration**

Through end of benefit year

**Other Criteria**

**Indications**

All Medically-accepted Indications.

**Off Label Uses**

**Drugs**  
**TRINTELLIX**

**Exclusion Criteria**

**Required Medical Information**

Diagnosis of major depressive disorder and treatment failure of at least two other formulary medications used in the treatment of major depressive disorder

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year.

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## Tukysa (Tucatinib)

---

### Drugs

**TUKYSA ORAL TABLET 150 MG, 50 MG**

### Exclusion Criteria

#### Required Medical Information

Used for medical treatment of Breast cancer, human epidermal growth factor receptor 2 positive, advanced unresectable or metastatic:advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-positive breast cancer (in combination with trastuzumab and capecitabine) in adults with or without brain metastases who have received 1 or more prior anti-HER2-based regimens in the metastatic setting.

### Age Restriction

### Prescriber Restriction

### Coverage Duration

Through end of benefit year

### Other Criteria

### Indications

All FDA-approved Indications.

### Off Label Uses

**Drugs**  
**TURALIO**

**Exclusion Criteria**

**Required Medical Information**

Documentation of symptomatic tenosynovial giant cell tumor (TGCT) associated with severe morbidity or functional limitations and not amenable to improvement with surgery.

**Age Restriction**

**Prescriber Restriction**

Oncologist

**Coverage Duration**

3 months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**



**Drugs**  
**TYKERB**

**Exclusion Criteria**

**Required Medical Information**

Diagnosis of breast cancer with tumors that overexpress human epidermal growth factor receptor 2 (HER2) AND 1. the medication will be used in combination with Xeloda in a patient with advanced or metastatic disease and the patient has received prior therapy including an anthracycline, a taxane, and trastuzumab, or 2) The medication will be used in combination with Femara for the treatment of a postmenopausal woman with hormone receptor-positive metastatic disease for whom hormonal therapy is indicated.

**Age Restriction**

18 years or older

**Prescriber Restriction**

Must be prescribed by Oncologist and Oncologist must monitor treatment

**Coverage Duration**

Initial: 3 months, Renewal: 6 months with documentation of continued benefit

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**TYMLOS**

**Exclusion Criteria**

**Required Medical Information**

Diagnosis of one of the following: A) Osteoporosis in a postmenopausal female AND one or more of the following: 1) History of osteoporotic fracture, or 2) Documented trial and failure of bisphosphonate or 3) Documented contraindication or intolerance to bisphosphonate therapy. Patient has not received more than 2 years of therapy with Tymlos.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Initial: 1 year. Renewal: 1 year not to exceed 2 years of total

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## Ubrelvy (Ubrogepant)

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### **Drugs** **UBRELVY**

#### **Exclusion Criteria**

#### **Required Medical Information**

Documentation that the medication will be used for the acute treatment of migraine with or without aura in adults AND the member has tried and failed two alternatives one of which was a triptan, unless contraindicated.

#### **Age Restriction**

#### **Prescriber Restriction**

#### **Coverage Duration**

Through end of benefit year

#### **Other Criteria**

Reauthorization requires documentation of medication efficacy.

#### **Indications**

All FDA-approved Indications.

#### **Off Label Uses**

**Drugs**

UPTRAVI ORAL TABLET, UPTRAVI ORAL TABLETS,DOSE PACK

**Exclusion Criteria**

**Required Medical Information**

Patient has a diagnosis of PAH (WHO Group I) WHO/NYHA Class IV patients OR 1.) Patient has a diagnosis of PAH (WHO Group I) WHO/NYHA Class II-III who do not respond adequately to, are unable to tolerate, or are not candidates for endothelin receptor antagonists (e.g. TRACLEER [bosentan] or LETAIRIS [ambrisentan]) and phosphodiesterase-5 (PDE-5) inhibitors (e.g. REVATIO [sildenafil], ADCIRCA [tadalafil]).

**Age Restriction**

Patient must be at least 18 years of age.

**Prescriber Restriction**

Prescribed by a pulmonologist or a cardiologist

**Coverage Duration**

3 Months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## VALCHLOR

---

### **Drugs** **VALCHLOR**

#### **Exclusion Criteria**

#### **Required Medical Information**

Documentated diagnosis of stage IA and IB mycosis fungoides-type cutaneous T-cell lymphoma in patients who have received prior skin-directed therapy.

#### **Age Restriction**

#### **Prescriber Restriction**

#### **Coverage Duration**

Through benefit year

#### **Other Criteria**

#### **Indications**

All FDA-approved Indications.

#### **Off Label Uses**

## Vancomycin

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### Drugs

*vancomycin oral capsule*

### Exclusion Criteria

#### Required Medical Information

Diagnosis of A) Clostridium difficile-associated diarrhea, AND Stool culture report within the previous 30 days indicating positive C. difficile toxin, or B) Staphylococcus aureus (including methicillin-resistant strains) enterocolitis

### Age Restriction

### Prescriber Restriction

### Coverage Duration

14 days, Patients with multiple relapses: 6 weeks

### Other Criteria

### Indications

All FDA-approved Indications.

### Off Label Uses

**Drugs**

VENCLEXTA ORAL TABLET 10 MG, 100 MG, 50 MG, VENCLEXTA STARTING PACK

**Exclusion Criteria**

**Required Medical Information**

Documented diagnosis of A) chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) or B) newly-diagnosed acute myeloid leukemia (AML) in adults who are age 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy and will be used in combination with azacitidine, decitabine, or low-dose cytarabine.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

3 months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**VENTAVIS**

**Exclusion Criteria**

**Required Medical Information**

Patient has a diagnosis of PAH (WHO Group I) WHO/NYHA Class IV patients OR 1.) Patient has a diagnosis of PAH (WHO Group I) WHO/NYHA Class II-III who do not respond adequately to, are unable to tolerate, or are not candidates for one endothelin receptor antagonists (e.g. TRACLEER [bosentan] or LETAIRIS [ambrisentan]) and one phosphodiesterase-5 (PDE-5) inhibitors (e.g. REVATIO [sildenafil], ADCIRCA [tadalafil]).

**Age Restriction**

18 years or older

**Prescriber Restriction**

Cardiologist or Pulmonologist

**Coverage Duration**

3 months initial, renewable every 6 months

**Other Criteria**

Ventavis is subject to Part B vs. Part D review.

**Indications**

All FDA-approved Indications.

**Off Label Uses**



**Drugs**  
**VERSACLOZ**

**Exclusion Criteria**

**Required Medical Information**

Refractory Schizophrenia/Schizoaffective Disorder: Versacloz will be approved upon receipt of physician statement that member requires the use of an atypical antipsychotic for the treatment of refractory schizophrenia that has failed to respond two courses of standard formulary antipsychotic agents or to reduce the risk of recurrent suicidal behavior in patients with schizophrenia or schizoaffective disorder AND is intolerant to oral solutions or unable to swallow other oral formulations. Formulary antipsychotics include: clozapine (tablet), risperidone (orally disintegrating tablet, tablet, solution), quetiapine (tablet), and olanzapine (tablet).

**Age Restriction**

18 years or older

**Prescriber Restriction**

Part of a clozapine registry

**Coverage Duration**

Through the benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**VERZENIO**

**Exclusion Criteria**

**Required Medical Information**

Documented diagnosis of one of the following: A) Hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer AND the patient is postmenopausal AND the medication is used in combination with an aromatase inhibitor as initial endocrine-based therapy, or B) hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer with disease progression following endocrine therapy AND being used in combination with fulvestrant, or C) as monotherapy for the treatment of adult patients with HR-positive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting.

**Age Restriction**

**Prescriber Restriction**

Oncologist

**Coverage Duration**

3 Months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**VIBERZI**

**Exclusion Criteria**

Documentation of gallbladder removal, known or suspected biliary duct obstruction, or a history of pancreatitis.

**Required Medical Information**

Diagnosis of irritable bowel syndrome with diarrhea and failed at least TWO alternatives from different classes such as antidiarrheals (e.g. loperamide), antispasmodics (e.g. dicyclomine).

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## VIIBRYD (vilazodone)

---

### Drugs

VIIBRYD ORAL TABLET 10 MG, 20 MG, 40 MG, VIIBRYD ORAL TABLETS,DOSE PACK 10 MG (7)- 20 MG (23)

### Exclusion Criteria

#### Required Medical Information

Documented trial of at least two generic antidepressants (e.g. bupropion, citalopram, escitalopram, fluoxetine, fluvoxamine, paroxetine, paroxetine CR, sertraline, duloxetine, venlafaxine).

### Age Restriction

### Prescriber Restriction

### Coverage Duration

Through end of benefit year

### Other Criteria

### Indications

All FDA-approved Indications.

### Off Label Uses

## VIMPAT

---

### Drugs

VIMPAT ORAL SOLUTION, VIMPAT ORAL TABLET

### Exclusion Criteria

#### Required Medical Information

Diagnosis of partial-onset seizures and treatment failure of at least two other formulary medications used in the treatment of partial onset seizures.

### Age Restriction

### Prescriber Restriction

#### Coverage Duration

Through end of benefit year

#### Other Criteria

Max dose 400mg/day

#### Indications

All FDA-approved Indications.

### Off Label Uses

## Vitrakvi (larotrectinib)

---

### Drugs

VITRAKVI ORAL CAPSULE 100 MG, 25 MG, VITRAKVI ORAL SOLUTION

### Exclusion Criteria

#### Required Medical Information

Clinical documentation of unresectable or metastatic solid tumors that have a neurotrophic receptor tyrosine kinase (NTRK) gene fusion and have no satisfactory alternative treatments or that have progressed following treatment.

### Age Restriction

#### Prescriber Restriction

Oncology

#### Coverage Duration

3 months

### Other Criteria

#### Indications

All FDA-approved Indications.

### Off Label Uses

**Drugs**  
**VIZIMPRO**

**Exclusion Criteria**

**Required Medical Information**

Documentation that medication will be used for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations as detected by an FDA-approved test.

**Age Restriction**

**Prescriber Restriction**

Oncology

**Coverage Duration**

3 months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## VORICONAZOLE

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### **Drugs**

*voriconazole oral*

### **Exclusion Criteria**

#### **Required Medical Information**

Documentation of invasive aspergillosis, bronchopulmonary aspergillosis, candidemia and disseminated candidiasis in skin, abdomen, kidney, bladder wall and wounds, esophageal candidiasis, and serious Candida infections, infections caused by the emerging pathogens *Scedosporium* sp. and *Fusarium* sp., or rare and refractory fungal infections should be provided. Preferred alternative for Candida: oral fluconazole

#### **Age Restriction**

2 years or older

#### **Prescriber Restriction**

#### **Coverage Duration**

6 months

#### **Other Criteria**

#### **Indications**

All Medically-accepted Indications.

#### **Off Label Uses**



**Drugs**  
**VOTRIENT**

**Exclusion Criteria**

**Required Medical Information**

Diagnosis of one of the following: A) Advanced/metastatic renal cell carcinoma, or B) Advanced soft tissue sarcoma and patient received at least one prior chemotherapy (e.g., doxorubicin, dacarbazine, ifosfamide, epirubicin, gemcitabine, docetaxel, or vinorelbine).

**Age Restriction**

18 years of age and older

**Prescriber Restriction**

Oncologist

**Coverage Duration**

Initial: 3 months, Renewal: 6 months with documentation of continued benefit

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## VRAYLAR (cariprazine)

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### Drugs

VRAYLAR ORAL CAPSULE, VRAYLAR ORAL CAPSULE,DOSE PACK

### Exclusion Criteria

#### Required Medical Information

Documented trial of any of the two following drugs: aripiprazole, clozapine, olanzapine, risperidone, quetiapine, ziprasidone

### Age Restriction

### Prescriber Restriction

#### Coverage Duration

Schizophrenia: Through end of benefit year, Bipolar disorder: 12 weeks

### Other Criteria

#### Indications

All FDA-approved Indications.

### Off Label Uses

**Drugs**  
**VUMERITY**

**Exclusion Criteria**

Concurrent use with other MS disease modifying agents (including Aubagio, Avonex, Betaseron, Copaxone/Glatiramer/Glatopa, Extavia, Gilenya, Lemtrada, Mavenclad, Mayzent, Ocrevus, Plegridy, Rebif, Tecfidera and Tysabri) OR Member with moderate or severe renal impairment (creatinine clearance less than 60 mL/min).

**Required Medical Information**

Documentation that the medication will be used for the treatment of relapsing forms of multiple sclerosis (MS)(including clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease).

**Age Restriction**

**Prescriber Restriction**

Neurologist

**Coverage Duration**

Benefit Year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**WAKIX**

**Exclusion Criteria**

**Required Medical Information**

Diagnosis of one of Excessive daytime sleepiness in patients with narcolepsy AND 1. Submission of sleep study with narcolepsy diagnosis, AND 2. currently NOT taking any sedative hypnotics or other CNS depressants AND 3. has experienced inadequate response or intolerable side effects to two preferred products (modafinil, armodofinil, methylphenidate, or dextroamphetamine).

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Initial: 3 months, Renewal: 6 months with documentation of continued benefit

**Other Criteria**

For renewal, the patient had a positive response to the medication (increased sleep quality for patients with narcolepsy).

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**XALKORI**

**Exclusion Criteria**

**Required Medical Information**

Documented diagnosis of metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK) or ROS1-positive as detected by an FDA-approved test

**Age Restriction**

18 years and older

**Prescriber Restriction**

Oncologist

**Coverage Duration**

3 months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**XATMEP**

**Exclusion Criteria**

**Required Medical Information**

Clinical documentation of acute lymphoblastic leukemia (ALL) or polyarticular juvenile ideopathic arthritis (pJIA). For the diagnosis of pJIA, the member must have had an adequate trial and failure of a full dose NSAID (minimum 12 weeks).

**Age Restriction**

Must be under 18 years of age.

**Prescriber Restriction**

pJIA indications from Rheumatologist  
All other indications from Oncologist

**Coverage Duration**

Through the end of the benefit year.

**Other Criteria**

Medication is eligible for B vs. D determination

**Indications**

All FDA-approved Indications.

**Off Label Uses**

## Xcopri (Cenobamate)

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### Drugs

XCOPRI MAINTENANCE PACK, XCOPRI ORAL TABLET 100 MG, 150 MG, 200 MG, 50 MG, XCOPRI TITRATION PACK

### Exclusion Criteria

#### Required Medical Information

Diagnosed with partial-onset seizures and treatment failure of at least two other formulary medications used in the treatment of partial onset seizures.

### Age Restriction

### Prescriber Restriction

### Coverage Duration

Through end of benefit year

### Other Criteria

### Indications

All FDA-approved Indications.

### Off Label Uses

**Drugs**

**XELJANZ ORAL TABLET, XELJANZ XR ORAL TABLET EXTENDED RELEASE 24 HR 11 MG, 22 MG**

**Exclusion Criteria**

**Required Medical Information**

Diagnosis of one of the following: A) Psoriatic Arthritis AND negative Tuberculin test prior to therapy AND patient is free of any clinically important active infections, or B) Rheumatoid Arthritis AND negative Tuberculin test prior to therapy AND patient is free of any clinically important active infections, or C) Ulcerative Colitis AND negative Tuberculin test prior to therapy AND patient is free of any clinically important active infections.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**



**Drugs**  
**XGEVA**

**Exclusion Criteria**

Hypocalcemia (calcium less than 8.0 mg/dL).

**Required Medical Information**

Diagnosis of one of the following: A) Multiple Myeloma and Bone Metastasis from solid tumors (e.g., breast cancer, castrate-resistant prostate cancer, thyroid carcinoma, kidney, or non-small cell lung cancer) and medication will be used for the prevention of skeletal-related events (e.g., spinal cord compression, hypercalcemia, bone pain or lesions requiring radiation or surgery), or B) Giant cell tumor of bone that is unresectable or surgical resection is likely to result in severe morbidity, or C) Treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy (i.e. alendronate, ibandronate, risedronate).

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

Medication is eligible for B vs. D determination

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**

**XIFAXAN ORAL TABLET 200 MG**

**Exclusion Criteria**

Allergy to rifamycin agents

**Required Medical Information**

Diagnosis of traveler's diarrhea and patient does not have fever or blood in the stool

**Age Restriction**

12 years of age or older

**Prescriber Restriction**

**Coverage Duration**

Traveler's diarrhea: 3 days

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**

**XIFAXAN ORAL TABLET 550 MG**

**Exclusion Criteria**

Allergy to rifamycin agents

**Required Medical Information**

Diagnosis of hepatic encephalopathy and tried and failed lactulose therapy OR Diagnosis of irritable bowel syndrome with diarrhea and failed at least TWO alternatives from different classes such as antidiarrheals (e.g. loperamide), antispasmodics (e.g. dicyclomine).

**Age Restriction**

Hepatic encephalopathy and IBS-D: 18 years of age or older

**Prescriber Restriction**

**Coverage Duration**

Hepatic encephalopathy: through benefit year, IBS-D: 6 weeks

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**XOLAIR**

**Exclusion Criteria**

**Required Medical Information**

Diagnosis of A) moderate to severe persistent allergic asthma AND Evidence of specific allergic sensitivity confirmed by positive skin test (i.e. prick/puncture test) or blood test (i.e. radioallergosorbent test) for a specific IgE or in vitro reactivity to a perennial aeroallergen AND Pretreatment serum IgE levels greater than 30 and less than 700 IU/mL for patients 12 years of age or older or greater than 30 and less than 1300 for patients 6 to 11 years of age AND Symptoms are not adequately controlled with at least ONE inhaled corticosteroid (ICS) plus long-acting beta2-agonist (LABA) (e.g. Advair, Symbicort) for at least 3 months unless patient is intolerant to such treatment or is contraindicated, or B) Treatment of chronic idiopathic urticaria in adults and adolescents 12 years and older who remain symptomatic despite H1 antihistamine treatment (i.e. loratidine, cetirizine, levocetirizine, fexofenadine, etc.).

**Age Restriction**

6 years of age or older

**Prescriber Restriction**

Initial drug order must be by an allergist/immunologist, dermatologist or a pulmonologist

**Coverage Duration**

6 months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**XOSPATA**

**Exclusion Criteria**

**Required Medical Information**

Clinical documentation of relapsed or refractory acute myeloid leukemia (AML) with a FMS-like tyrosine kinase 3 (FLT3) mutation as detected by an FDA-approved test.

**Age Restriction**

**Prescriber Restriction**

Oncology

**Coverage Duration**

3 months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**

XPOVIO ORAL TABLET 100 MG/WEEK (20 MG X 5), 40 MG/WEEK (20 MG X 2), 40MG TWICE WEEK (80 MG/WEEK), 60 MG/WEEK (20 MG X 3), 60MG TWICE WEEK (120 MG/WEEK), 80 MG/WEEK (20 MG X 4), 80MG TWICE WEEK (160 MG/WEEK)

**Exclusion Criteria**

**Required Medical Information**

Documentation that the medication will be used in 1) combination with dexamethasone for the treatment of adult patients with relapsed or refractory multiple myeloma (RRMM) who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody. OR 2) monotherapy for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma

**Age Restriction**

**Prescriber Restriction**

Oncologist

**Coverage Duration**

3 months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**XTANDI**

**Exclusion Criteria**

**Required Medical Information**

Diagnosis of A) Metastatic castration-resistant prostate cancer AND the patient has tried and had an inadequate response, contraindication or intolerance to abiraterone OR B) Non- metastatic Castration-resistant prostate cancer (CRPC) OR C) metastatic castration-sensitive prostate cancer.

**Age Restriction**

**Prescriber Restriction**

Oncologist or urologist

**Coverage Duration**

3 Months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**XYREM**

**Exclusion Criteria**

Contraindications: Patient is being treated with sedative hypnotic agents, other CNS depressants, or using alcohol. Patient has succinic semialdehyde dehydrogenase deficiency.

**Required Medical Information**

Diagnosis of one of the following: A) Excessive daytime sleepiness in patients with narcolepsy AND 1. Submission of sleep study with narcolepsy diagnosis, AND 2. currently NOT taking any sedative hypnotics or other CNS depressants AND 3. has experienced inadequate response or intolerable side effects to two preferred products (modafinil, armodafinil, methylphenidate, or dextroamphetamine) AND 4. The requested dose does not exceed the FDA indicated maximum (9gm/night), or B) Cataplexy in patients with narcolepsy AND 1. Submission of sleep study showing narcolepsy diagnosis, AND 2. currently NOT taking any sedative hypnotics or other CNS depressants, AND 3. does not have sleep apnea, AND 4. The dose does not exceed the FDA indicated maximum (9gm/night).

**Age Restriction**

7 years of age or older

**Prescriber Restriction**

**Coverage Duration**

Initial: 3 months, Renewal: 6 months with documentation of continued benefit

**Other Criteria**

Patient and physician must adhere to all regulations of the Xyrem REMS Program. For renewal, the patient had a positive response to the medication (increased sleep quality for patients with narcolepsy).

**Indications**

All FDA-approved Indications.

**Off Label Uses**



**Drugs**  
**YONSA**

**Exclusion Criteria**

**Required Medical Information**

Documented diagnosis of metastatic castration resistant prostate cancer (CRPC) AND the medication is being used in combination with methylprednisolone AND medication not being used as dual therapy with another androgen receptor inhibitor.

**Age Restriction**

18 years of age or older

**Prescriber Restriction**

**Coverage Duration**

3 Months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
*miglustat*

**Exclusion Criteria**

**Required Medical Information**

Diagnosis of mild to moderate type 1 Gaucher disease for whom enzyme replacement therapy is not a therapeutic option (e.g., due to constraints such as allergy, hypersensitivity, or poor venous access).

**Age Restriction**

18 years or older

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**ZEJULA**

**Exclusion Criteria**

**Required Medical Information**

Documented diagnosis of 1) recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer in a complete or partial response to platinum-based chemotherapy OR 2) advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy OR 3) advanced ovarian, fallopian tube, or primary peritoneal cancer who have been treated with three or more prior chemotherapy regimens and whose cancer is associated with homologous recombination deficiency (HRD) positive status.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

Through end of benefit year

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**ZELBORAF**

**Exclusion Criteria**

Combination use with ipilimumab

**Required Medical Information**

Diagnosis of A) unresectable or metastatic melanoma whose tumors express a gene mutation called BRAF V600E detected by an FDA approved test. Vemurafenib is not recommended for use in patients with wild-type BRAF melanoma. OR B) Erdheim-Chester Disease (ECD) with BRAF V600 mutation.

**Age Restriction**

18 years or older

**Prescriber Restriction**

Oncologist

**Coverage Duration**

3 months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**

**ZEPOSIA, ZEPOSIA STARTER KIT, ZEPOSIA STARTER PACK**

**Exclusion Criteria**

**Required Medical Information**

Documentation of diagnosis of relapsing multiple sclerosis, including relapsing-remitting disease, clinically-isolated syndrome, and active secondary progressive disease AND a complete blood cell count and liver function test was completed, reviewed, and deemed appropriate for Zeposia treatment by the prescriber AND patient has had ECG to assess for preexisting cardiac conduction abnormalities prior to starting Zeposia AND inadequate response or intolerance to at least one alternative drug indicated for the treatment of multiple sclerosis.

**Age Restriction**

18 Years of age and older

**Prescriber Restriction**

Neurologist

**Coverage Duration**

Initial 3 months, Continuation of therapy: 12 months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**ZYDELIG**

**Exclusion Criteria**

**Required Medical Information**

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**  
Through end of benefit year.

**Other Criteria**

**Indications**  
All FDA-approved Indications.

**Off Label Uses**

**Drugs**  
**ZYKADIA ORAL TABLET**

**Exclusion Criteria**

**Required Medical Information**

Documented diagnosis of metastatic non-small cell lung cancer (NSCLC) whose tumors are anaplastic lymphoma kinase (ALK)-positive as detected by an FDA-approved test

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

3 months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Drugs**

*abiraterone oral tablet 250 mg, 500 mg*

**Exclusion Criteria**

**Required Medical Information**

Diagnosis of one of the following: A) metastatic prostate cancer AND Patient has castration-resistant disease (defined by tumor growth/disease progression, risk in PsA levels, new metastases) AND abiraterone will be used in combination with prednisone, or B) Metastatic high-risk castration-sensitive prostate cancer AND abiraterone will be used in combination with prednisone.

**Age Restriction**

**Prescriber Restriction**

**Coverage Duration**

3 months

**Other Criteria**

**Indications**

All FDA-approved Indications.

**Off Label Uses**



**Drugs**

*linezolid*

**Exclusion Criteria**

**Required Medical Information**

Culture and sensitivity reports verifying: 1. VRE infections within past 30 days. 2. Nosocomial pneumonia (MRSA) within past 30 days. 3. Nosocomial or CAP (MSSA or *S. pneumoniae*) within past 30 days and failure/resistance to 2 preferred antibiotics. 4. Complicated SSI without osteomyelitis (MRSA) within past 30 days. 5. Uncomplicated SSI (MRSA) within past 30 days or empirical treatment of uncomplicated or community-acquired complicated SSI without osteomyelitis (MRSA likely) and failure/resistance to 2 preferred antibiotics. 6. Uncomplicated or complicated SSI without osteomyelitis (MSSA, *S. pyogenes*, or *S. agalactiae* (complicated SSI only)) within past 30 days and failure/resistance to 2 preferred antibiotics.

**Age Restriction**

**Prescriber Restriction**

Prescribing physician must be an infectious disease specialist

**Coverage Duration**

Non-MRSA nosocomial or community acquired pneumonia, SSI: 14 days Other uses: 28 days

**Other Criteria**

Nosocomial or community acquired pneumonia (MSSA or *S. pneumoniae*) preferred antibiotics: Amoxicillin/Clavulanate, Azithromycin, Cephalexin, Clarithromycin, Levaquin. Uncomplicated SSI (MRSA) or empirical treatment of patients with uncomplicated or community-acquired complicated SSI without osteomyelitis (MRSA likely) preferred antibiotics: Trimethoprim/sulfamethoxazole, Tetracycline, Doxycycline, Minocycline, Clindamycin. Uncomplicated or complicated SSI without osteomyelitis (MSSA, *S. pyogenes*, or *S. agalactiae* (complicated SSI only)) preferred antibiotics: Amoxicillin/clavulanate, Cephalexin, Ciprofloxacin, Clindamycin, Levaquin, Trimethoprim/Sulfamethoxazole, Dicloxacillin.

**Indications**

All FDA-approved Indications.

**Off Label Uses**

**Index**

<b>ABILIFY MAINTENA</b> ..... 25	<b>CAPRELSA ORAL TABLET 100</b>	<b>EPIDIOLEX</b> ..... 62
<i>abiraterone oral tablet 250 mg, 500</i>	<b>MG, 300 MG</b> ..... 36	<b>ERIVEDGE</b> ..... 64
<i>mg</i> ..... 280	<b>CARBAGLU</b> ..... 37	<b>ERLEADA</b> ..... 65
<i>acitretin</i> ..... 2	<i>caspofungin</i> ..... 35	<i>erlotinib</i> ..... 221
<b>ACTIMMUNE</b> ..... 3	<b>CAYSTON</b> ..... 38	<b>ESBRIET ORAL CAPSULE</b> ..... 66
<b>ADEMPAS</b> ..... 4	<b>CINRYZE</b> ..... 39	<b>ESBRIET ORAL TABLET 267 MG,</b>
<b>AFINITOR</b> ..... 5	<i>clemastine oral tablet 2.68 mg</i> ..... 91	<b>801 MG</b> ..... 66
<b>AFINITOR DISPERZ</b> ..... 5	<b>CLOVIQUE</b> ..... 40	<i>estradiol-norethindrone acet oral</i>
<b>AIMOVIG AUTOINJECTOR</b> ..... 33	<i>clozapine oral tablet, disintegrating</i> ...73	<i>tablet 1-0.5 mg</i> ..... 97
<b>AJOVY AUTOINJECTOR</b> ..... 33	<b>COMETRIQ ORAL CAPSULE 100</b>	<b>EVENITY SUBCUTANEOUS</b>
<b>AJOVY SYRINGE</b> ..... 33	<b>MG/DAY(80 MG X1-20 MG X1),</b>	<b>SYRINGE 210MG/2.34ML (</b>
<b>ALECENSA</b> ..... 6	<b>140 MG/DAY(80 MG X1-20 MG</b>	<b>105MG/1.17MLX2)</b> ..... 67
<i>alosectron</i> ..... 7	<b>X3), 60 MG/DAY (20 MG X 3/DAY)</b> .41	<i>everolimus (antineoplastic)</i> ..... 5
<b>ALUNBRIG ORAL TABLET 180</b>	<b>COPIKTRA</b> ..... 43	<b>EVRYSDI</b> ..... 68
<b>MG, 30 MG, 90 MG</b> .....8	<b>CORLANOR</b> ..... 44	<b>FANAPT ORAL TABLET</b> ..... 70
<b>ALUNBRIG ORAL</b>	<b>COSENTYX (2 SYRINGES)</b> ..... 45	<b>FANAPT ORAL TABLETS,DOSE</b>
<b>TABLETS,DOSE PACK</b> ..... 8	<b>COSENTYX PEN (2 PENS)</b> .....45	<b>PACK</b> ..... 70
<i>ambrisentan</i> ..... 131	<b>COTELLIC</b> ..... 46	<b>FARYDAK</b> ..... 71
<b>ANADROL-50</b> ..... 10	<i>cyproheptadine oral tablet</i> .....91	<b>FASENRA</b> ..... 72
<b>APOKYN</b> ..... 11	<b>CYTAGON</b> ..... 47	<b>FASENRA PEN</b> ..... 72
<b>APTIOM</b> ..... 12	<b>CYSTARAN</b> ..... 48	<i>fentanyl citrate buccal lozenge on a</i>
<b>ARCALYST</b> ..... 13	<i>dalfampridine</i> ..... 9	<i>handle</i> ..... 74
<b>ARISTADA INTRAMUSCULAR</b>	<b>DAURISMO ORAL TABLET 100</b>	<b>FERRIPROX ORAL TABLET</b> .....75
<b>SUSPENSION,EXTENDED REL</b>	<b>MG, 25 MG</b> ..... 49	<b>FETZIMA</b> ..... 76
<b>SYRING 441 MG/1.6 ML</b> ..... 25	<i>deferasirox oral tablet, dispersible</i> ... 69	<b>FINTEPLA</b> ..... 77
<i>asenapine maleate</i> ..... 199	<i>deferiprone</i> ..... 50	<b>FIRDAPSE</b> ..... 79
<b>AUBAGIO</b> ..... 14	<b>DEMSEER</b> ..... 51	<b>FORTEO</b> ..... 80
<b>AUSTEDO ORAL TABLET 12 MG,</b>	<b>DIACOMIT</b> ..... 52	<b>FYCOMPA ORAL SUSPENSION</b> ... 81
<b>6 MG, 9 MG</b> ..... 15	<b>DIFICID ORAL TABLET</b> ..... 53	<b>FYCOMPA ORAL TABLET 10</b>
<b>AVONEX INTRAMUSCULAR PEN</b>	<i>dimethyl fumarate oral</i>	<b>MG, 12 MG, 2 MG, 4 MG, 6 MG, 8</b>
<b>INJECTOR KIT</b> ..... 16	<i>capsule, delayed release(DR/EC)</i>	<b>MG</b> ..... 81
<b>AVONEX INTRAMUSCULAR</b>	<i>120 mg, 240 mg</i> ..... 54	<b>GARDASIL 9 (PF)</b> ..... 82
<b>SYRINGE KIT</b> ..... 16	<i>dipyridamole oral</i> .....98	<b>GATTEX 30-VIAL</b> ..... 83
<b>AYVAKIT</b> ..... 17	<i>disopyramide phosphate oral</i>	<b>GAVRETO</b> ..... 84
<b>BALVERSA</b> ..... 18	<i>capsule</i> .....90	<b>GEODON INTRAMUSCULAR</b> ..... 25
<b>BANZEL ORAL SUSPENSION</b> ..... 19	<b>DOPTELET (10 TAB PACK)</b> ..... 55	<b>GILENYA ORAL CAPSULE 0.5</b>
<b>BANZEL ORAL TABLET 200 MG,</b>	<b>DOPTELET (15 TAB PACK)</b> ..... 55	<b>MG</b> ..... 85
<b>400 MG</b> ..... 19	<b>DOPTELET (30 TAB PACK)</b> ..... 55	<b>GILOTRIF</b> ..... 86
<b>BENLYSTA SUBCUTANEOUS</b> ..... 20	<i>doxepin oral capsule 10 mg, 100</i>	<b>GIMOTI</b> ..... 87
<i>benznidazole</i> ..... 21	<i>mg, 150 mg, 25 mg, 50 mg, 75 mg</i> ..99	<i>glatiramer subcutaneous syringe</i>
<b>BETASERON SUBCUTANEOUS</b>	<i>doxepin oral concentrate 10 mg/mL</i> ..99	<i>20 mg/mL, 40 mg/mL</i> ..... 42
<b>KIT</b> ..... 22	<i>dronabinol</i> ..... 56	<b>GLATOPA SUBCUTANEOUS</b>
<i>bosentan</i> ..... 235	<b>DUAVEE</b> ..... 97	<b>SYRINGE 20 MG/ML, 40 MG/ML</b> .... 42
<b>BOSULIF ORAL TABLET 100</b>	<b>DUPIXENT PEN</b> ..... 57	<b>HETLIOZ</b> ..... 89
<b>MG, 400 MG, 500 MG</b> ..... 23	<b>DUPIXENT SYRINGE</b>	<b>HUMIRA PEN</b> ..... 100
<b>BRAFTOVI ORAL CAPSULE 75</b>	<b>SUBCUTANEOUS SYRINGE 200</b>	<b>HUMIRA PEN CROHNS-UC-HS</b>
<b>MG</b> ..... 24	<b>MG/1.14 ML, 300 MG/2 ML</b> ..... 57	<b>START</b> ..... 100
<b>BRIVIACT ORAL SOLUTION</b> ..... 26	<b>EMSAM</b> ..... 58	<b>HUMIRA PEN PSOR-UEVITS-</b>
<b>BRIVIACT ORAL TABLET 10 MG,</b>	<b>ENBREL MINI</b> ..... 59	<b>ADOL HS</b> ..... 100
<b>100 MG, 25 MG, 50 MG, 75 MG</b> ..... 26	<b>ENBREL SUBCUTANEOUS</b>	<b>HUMIRA SUBCUTANEOUS</b>
<b>BRUKINSA</b> ..... 27	<b>RECON SOLN</b> ..... 59	<b>SYRINGE KIT 40 MG/0.8 ML</b> ..... 100
<b>BYNFEZIA</b> ..... 30	<b>ENBREL SUBCUTANEOUS</b>	<b>HUMIRA(CF) PEN CROHNS-UC-</b>
<b>CABLIVI INJECTION KIT</b> ..... 31	<b>SOLUTION</b> ..... 59	<b>HS</b> ..... 100
<b>CABOMETYX ORAL TABLET 20</b>	<b>ENBREL SUBCUTANEOUS</b>	<b>HUMIRA(CF) PEN PSOR-UV-</b>
<b>MG, 40 MG, 60 MG</b> ..... 32	<b>SYRINGE 25 MG/0.5 ML (0.5), 50</b>	<b>ADOL HS</b> ..... 100
<b>CALQUENCE</b> ..... 34	<b>MG/ML (1 ML)</b> ..... 59	<b>HUMIRA(CF) PEN</b>
<b>CANCIDAS</b> ..... 35	<b>ENBREL SURECLICK</b> ..... 59	<b>SUBCUTANEOUS PEN</b>
<b>CAPLYTA</b> ..... 25	<b>ENDARI</b> ..... 60	<b>INJECTOR KIT 40 MG/0.4 ML, 80</b>
	<b>ENSPRYNG</b> ..... 61	<b>MG/0.8 ML</b> ..... 100

HUMIRA(CF) SUBCUTANEOUS SYRINGE KIT 10 MG/0.1 ML, 20 MG/0.2 ML, 40 MG/0.4 ML	100	KUVAN ORAL TABLET, SOLUBLE	125	NOURIANZ	154
<i>hydroxyzine HCl oral solution 10 mg/5 mL</i>	91	KYNMOBI SUBLINGUAL FILM 10 MG, 15 MG, 20 MG, 25 MG, 30 MG	126	NOXAFIL ORAL TABLET, DELAYED RELEASE (DR/EC)	155
IBRANCE	101	<i>lapatinib</i>	127	NUBEQA	156
<i>icatibant</i>	78	LATUDA ORAL TABLET 120 MG, 20 MG, 40 MG, 60 MG, 80 MG	128	NUCALA	157
ICLUSIG ORAL TABLET 10 MG, 30 MG	103	<i>ledipasvir-sofosbuvir</i>	129	NUDEXTA	158
ICLUSIG ORAL TABLET 15 MG, 45 MG	102	LENVIMA ORAL CAPSULE 10 MG/DAY (10 MG X 1), 12 MG/DAY (4 MG X 3), 14 MG/DAY (10 MG X 1-4 MG X 1), 18 MG/DAY (10 MG X 1-4 MG X 2), 20 MG/DAY (10 MG X 2), 24 MG/DAY (10 MG X 2-4 MG X 1), 4 MG, 8 MG/DAY (4 MG X 2)	130	NUPLAZID ORAL CAPSULE	159
IDHIFA	104	LEUKINE INJECTION RECON SOLN	132	NUPLAZID ORAL TABLET 10 MG	159
<i>imatinib oral tablet 100 mg, 400 mg</i>	88	<i>lidocaine topical adhesive patch, medicated 5 %</i>	133	NURTEC ODT	160
IMBRUVICA ORAL CAPSULE 140 MG, 70 MG	105	<i>lidocaine topical ointment</i>	133	NYMALIZE ORAL SYRINGE 60 MG/10 ML	161
IMBRUVICA ORAL TABLET	105	<i>linezolid</i>	281	ODOMZO	162
INBRIJA INHALATION CAPSULE, W/INHALATION DEVICE	106	LOKELMA	134	OFEV	163
INCRELEX	107	LONSURF ORAL TABLET 15-6.14 MG, 20-8.19 MG	135	OMNITROPE SUBCUTANEOUS CARTRIDGE	164
INGREZZA	108	LORBRENA ORAL TABLET 100 MG, 25 MG	136	ONUREG	165
INGREZZA INITIATION PACK	108	LUPRON DEPOT	137	OPSUMIT	166
INLYTA ORAL TABLET 1 MG, 5 MG	109	LUPRON DEPOT (3 MONTH)	137	ORENCIA CLICKJECT	167
INQOVI	110	LUPRON DEPOT (4 MONTH)	137	ORENCIA SUBCUTANEOUS SYRINGE 125 MG/ML, 50 MG/0.4 ML, 87.5 MG/0.7 ML	167
INREBIC	111	LUPRON DEPOT (6 MONTH)	137	ORENITRAM	168
INTRON A INJECTION RECON SOLN 18 MILLION UNIT (1 ML), 50 MILLION UNIT (1 ML)	112	LYNPARZA ORAL TABLET	138	ORGOVYX	169
INVEGA SUSTENNA	113	MAVENCLAD (10 TABLET PACK)	139	ORKAMBI ORAL TABLET	170
INTRAMUSCULAR SYRINGE 117 MG/0.75 ML, 156 MG/ML, 234 MG/1.5 ML, 39 MG/0.25 ML, 78 MG/0.5 ML	113	MAVENCLAD (4 TABLET PACK)	139	OTEZLA	171
IRESSA	114	MAVENCLAD (5 TABLET PACK)	139	OTEZLA STARTER ORAL TABLETS, DOSE PACK 10 MG (4)-20 MG (4)-30 MG (47)	171
ISTURISA ORAL TABLET 1 MG, 10 MG, 5 MG	115	MAVENCLAD (6 TABLET PACK)	139	<i>oxandrolone oral tablet 10 mg, 2.5 mg</i>	172
<i>itraconazole oral capsule</i>	116	MAVENCLAD (7 TABLET PACK)	139	OXBRYTA	173
JAKAFI	117	MAVENCLAD (8 TABLET PACK)	139	OXERVATE	174
JUXTAPID ORAL CAPSULE 10 MG, 20 MG, 30 MG, 5 MG	118	MAVENCLAD (9 TABLET PACK)	139	<i>paliperidone oral tablet extended release 24hr 1.5 mg, 3 mg, 6 mg, 9 mg</i>	113
JYNARQUE ORAL TABLETS, SEQUENTIAL	119	MAVYRET	140	PALYNZIQ	175
KALYDECO ORAL GRANULES IN PACKET 25 MG, 50 MG, 75 MG	120	MEKINIST ORAL TABLET 0.5 MG, 2 MG	141	PEGASYS SUBCUTANEOUS SOLUTION	177
KALYDECO ORAL TABLET	120	MEKTOVI	142	PEGASYS SUBCUTANEOUS SYRINGE	177
KESIMPTA PEN	121	MENEST ORAL TABLET 0.3 MG, 0.625 MG, 1.25 MG	97	PEMAZYRE	178
KISQALI FEMARA CO-PACK ORAL TABLET 200 MG/DAY (200 MG X 1)-2.5 MG, 400 MG/DAY (200 MG X 2)-2.5 MG, 600 MG/DAY (200 MG X 3)-2.5 MG	122	<i>meprobamate</i>	96	PENNSAID TOPICAL SOLUTION IN METERED-DOSE PUMP	233
KISQALI ORAL TABLET 200 MG/DAY (200 MG X 1), 400 MG/DAY (200 MG X 2), 600 MG/DAY (200 MG X 3)	122	<i>metyrosine</i>	143	<i>perphenazine-amitriptyline</i>	99
KORLYM	123	<i>miglustat</i>	274	PERSERIS	179
KOSELUGO	124	<i>molindone</i>	144	<i>phenobarbital</i>	94
		NATPARA	145	PIQRAY ORAL TABLET 200 MG/DAY (200 MG X 1), 250 MG/DAY (200 MG X 1-50 MG X 1), 300 MG/DAY (150 MG X 2)	180
		NERLYNX	146	POMALYST	181
		NEULASTA	147	<i>posaconazole oral tablet, delayed release (DR/EC)</i>	182
		NEXAVAR	148	PRALUENT PEN	176
		NEXLETOL	149	PREMARIN ORAL	97
		NEXLIZET	150	PREMPHASE	97
		<i>nifedipine oral capsule</i>	95	PREMPRO	97
		NINLARO	151		
		<i>nitisinone</i>	152		
		NORTHERA	153		

PROCRIT INJECTION SOLUTION			
10,000 UNIT/ML, 2,000 UNIT/ML,			
20,000 UNIT/ML, 3,000 UNIT/ML,			
4,000 UNIT/ML, 40,000 UNIT/ML	63		
PROMACTA ORAL POWDER IN			
PACKET 12.5 MG	183		
PROMACTA ORAL TABLET	183		
<i>promethazine oral</i>	91		
<i>promethazine rectal suppository</i>			
12.5 mg, 25 mg	91		
PROMETHEGAN RECTAL			
SUPPOSITORY 25 MG, 50 MG	91		
PULMOZYME	184		
PURIXAN	185		
QINLOCK	186		
<i>quinine sulfate</i>	187		
RAVICTI	188		
REPATHA PUSHTRONEX	176		
REPATHA SURECLICK	176		
REPATHA SYRINGE	176		
RETEVMO ORAL CAPSULE 40			
MG, 80 MG	189		
REVLIMID	190		
REXULTI	25		
REYVOW	191		
RINVOQ	192		
RISPERDAL CONSTA	193		
ROZLYTREK	194		
RUBRACA	195		
<i>rufinamide</i>	19		
RYDAPT	196		
SAMSCA	198		
SAPHRIS	199		
<i>sapropterin oral tablet, soluble</i>	200		
SECUADO	201		
SEROSTIM SUBCUTANEOUS			
RECON SOLN 4 MG, 5 MG, 6 MG	202		
SIGNIFOR	203		
<i>sildenafil (pulm.hypertension) oral</i>			
<i>tablet</i>	204		
SIRTURO	205		
SKYRIZI SUBCUTANEOUS			
SYRINGE KIT	206		
<i>sodium phenylbutyrate oral tablet</i>	28		
<i>sofosbuvir-velpatasvir</i>	207		
SOMATULINE DEPOT	208		
SPRYCEL	209		
STELARA SUBCUTANEOUS	210		
STIVARGA	211		
SUCRAID	212		
SUNOSI	213		
SUTENT	214		
SYMPAZAN	215		
SYNRIBO	216		
TABRECTA	217		
TAFINLAR ORAL CAPSULE 50			
MG, 75 MG	218		
TAGRISSO	219		
TALZENNA ORAL CAPSULE 0.25			
MG, 1 MG	220		
TARGRETIN TOPICAL	222		
TASIGNA	223		
TAVALISSE	224		
<i>tazarotene</i>	234		
TAZORAC TOPICAL CREAM 0.05			
%	234		
TAZORAC TOPICAL GEL	234		
TAZVERIK	225		
TECFIDERA ORAL			
CAPSULE, DELAYED			
RELEASE(DR/EC) 120 MG, 120			
MG (14)- 240 MG (46), 240 MG	226		
TEGSEDI	227		
TENCON ORAL TABLET 50-325			
MG	29		
<i>teriparatide</i>	228		
THALOMID	229		
<i>thioridazine</i>	93		
TIBSOVO	230		
TOBI PODHALER INHALATION			
CAPSULE, W/INHALATION			
DEVICE	231		
<i>tolvaptan</i>	232		
TRACLEER ORAL TABLET FOR			
SUSPENSION	235		
<i>tretinoin</i>	234		
<i>trientine</i>	236		
<i>trihexyphenidyl</i>	92		
TRIKAFTA	237		
TRINTELLIX	238		
TUKYSA ORAL TABLET 150 MG,			
50 MG	239		
TURALIO	240		
TYKERB	241		
TYMLOS	242		
UBRELVY	243		
UPTRAVI ORAL TABLET	244		
UPTRAVI ORAL TABLETS, DOSE			
PACK	244		
VALCHLOR	245		
<i>vancomycin oral capsule</i>	246		
VENCLEXTA ORAL TABLET 10			
MG, 100 MG, 50 MG	247		
VENCLEXTA STARTING PACK	247		
VENTAVIS	248		
VERSACLOZ	249		
VERZENIO	250		
VIBERZI	251		
<i>vigabatrin</i>	197		
VIIBRYD ORAL TABLET 10 MG,			
20 MG, 40 MG	252		
VIIBRYD ORAL TABLETS, DOSE			
PACK 10 MG (7)- 20 MG (23)	252		
VIMPAT ORAL SOLUTION	253		
VIMPAT ORAL TABLET	253		
VITRAKVI ORAL CAPSULE 100			
MG, 25 MG	254		
VITRAKVI ORAL SOLUTION	254		
VIZIMPRO	255		
<i>voriconazole oral</i>	256		
VOTRIENT	257		
VRAYLAR ORAL CAPSULE	258		
VRAYLAR ORAL			
CAPSULE, DOSE PACK	258		
VTOL LQ	29		
VUMERITY	259		
WAKIX	260		
XALKORI	261		
XATMEP	262		
XCOPRI MAINTENANCE PACK	263		
XCOPRI ORAL TABLET 100 MG,			
150 MG, 200 MG, 50 MG	263		
XCOPRI TITRATION PACK	263		
XELJANZ ORAL TABLET	264		
XELJANZ XR ORAL TABLET			
EXTENDED RELEASE 24 HR 11			
MG, 22 MG	264		
XGEVA	265		
XIFAXAN ORAL TABLET 200 MG			
	266		
XIFAXAN ORAL TABLET 550 MG			
	267		
XOLAIR	268		
XOSPATA	269		
XPOVIO ORAL TABLET 100			
MG/WEEK (20 MG X 5), 40			
MG/WEEK (20 MG X 2), 40MG			
TWICE WEEK (80 MG/WEEK), 60			
MG/WEEK (20 MG X 3), 60MG			
TWICE WEEK (120 MG/WEEK),			
80 MG/WEEK (20 MG X 4), 80MG			
TWICE WEEK (160 MG/WEEK)	270		
XTANDI	271		
XYREM	272		
YONSA	273		
ZEJULA	275		
ZELBORAF	276		
ZEPOSIA	277		
ZEPOSIA STARTER KIT	277		
ZEPOSIA STARTER PACK	277		
ZYDELIG	278		
ZYKADIA ORAL TABLET	279		
ZYPREXA RELPREVV			
INTRAMUSCULAR SUSPENSION			
FOR RECONSTITUTION 210 MG	25		

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Y0089\_MPINFO7271AH\_C(04/19)

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**Arabic:**

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 1-877-535-8278 (رقم هاتف الصم والبكم: 1-800-955-8771).

**Italian:** ATTENZIONE: In caso la lingua parlata sia l'italiano, sono disponibili servizi di assistenza linguistica gratuiti. Chiamare il numero 1-877-535-8278 (TTY: 1-800-955-8771).

**German:** ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1-877-535-8278 (TTY: 1-800-955-8771).

**Korean:** 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1-877-535-8278 (TTY: 1-800-955-8771)번으로 전화해 주십시오.

**Polish:** UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 1-877-535-8278 (TTY: 1-800-955-8771).

**Gujarati:** સુચના: જો તમે ગુજરાતી બોલતા હો, તો નિ:શુલ્ક ભાષા સહાય સેવાઓ તમારા માટે ઉપલબ્ધ છે. ફોન કરો 1-877-535-8278 (TTY: 1-800-955-8771).

**Thai:** เรียน: ถ้าคุณพูดภาษาไทยคุณสามารถใช้บริการช่วยเหลือทางภาษาได้ฟรี โทร 1-877-535-8278 (TTY: 1-800-955-8771).

AdventHealth Advantage Plans is administered by Health First Health Plans. Health First Health Plans is an HMO plan with a Medicare contract. Enrollment in Health First Health Plans depends on contract renewal.